

SUBCHAPTER E—FELLOWSHIPS, INTERNSHIPS, TRAINING

PART 61—FELLOWSHIPS

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Subpart A—Regular Fellowships

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, sec. 8, 77 Stat. 400; 42 U.S.C. 216, 1857g; secs. 301, 402, 58 Stat. 691, as amended, 707, secs. 412, 422, 62 Stat. 464, 598, sec. 433, 64 Stat. 444, as amended, sec. 308, 74 Stat. 364, sec. 444, 76 Stat. 1073, sec. 3, 77 Stat. 394, secs. 394, 395, 79 Stat. 1062; 42 U.S.C. 241, 282, 287a, 288a, 289c, 242f, 289g, 1857b, 280b-4, 280b-5.

SOURCE: 31 FR 12096, Sept. 16, 1966, unless otherwise noted.

§ 61.1 Definitions.

As used in this part:

(a) *Continuation award* is an award made by the Surgeon General, within the period of support recommended by a fellowship committee, without necessity for further action by the committee.

(b) *Noncitizen national* means any person who, though not a citizen of the United States, owes permanent allegiance to the United States.

(c) *Regular fellowship* means an award to support activity not requiring performance of services for the Public Health Service.

(d) *Surgeon General* means the Surgeon General of the U.S. Public Health Service or his delegate.

(e) *Continental United States* does not include Hawaii or Alaska.

§ 61.2 Applicability.

The regulations in this subpart apply to the establishment, award, and operation of all regular fellowships awarded under the Public Health Service Act and the Clean Air Act.

§ 61.3 Purpose of regular fellowships.

Regular fellowships are provided to encourage and promote:

(a) Research and training for research relating to (1) the physical and mental diseases and impairments of man, (2) the organization, provision, and financing of health services, (3) the causes, prevention, and control of air pollution, and (4) medical library and related health sciences and communication of information.

(b) Special scientific projects for the compilation of existing, or writing of original, contributions relating to scientific, social, or cultural advancements in sciences related to health.

§ 61.4 Establishment and conditions.

All regular fellowships in the Public Health Service shall be established by the Surgeon General. In establishing a fellowship or series of fellowships, the Surgeon General shall prescribe in

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writing the conditions (in addition to those provided in the regulations in this part) under which the fellowships are to be awarded and held.

§ 61.5 Qualifications.

In order to qualify for a regular fellowship, an applicant must:

(a) Meet the Public Health Service requirements of general suitability, including professional and personal fitness.

(b) Have been accepted by a public or other nonprofit institution for the purpose of the activity for which the fellowship is sought.

(c) Be free from any disease or disability that would interfere with the accomplishment of the fellowship purpose.

(d) If a citizen or noncitizen national of the United States, sign and file with the Surgeon General the following statement:

I do solemnly swear (or affirm) that I bear true faith and allegiance to the United States of America and will support and defend the Constitution and laws of the United States against all its enemies, foreign and domestic.

(e) Comply with such other requirements as may be prescribed by the Surgeon General.

§ 61.6 Method of application.

Application for a regular fellowship shall be made on forms prescribed by the Surgeon General. In addition to the information supplied by the applicant in his application, such further information may be required as is necessary to determine his qualifications and fitness.

§ 61.7 Review of applications; committees; awards.

The Surgeon General shall appoint one or more fellowship committees to examine the qualifications of applicants for fellowships and the merits of their proposals for research, training, or special scientific projects. A fellowship committee shall submit to the Surgeon General its recommendations concerning appointments. Awards of regular fellowships shall be made in writing by the Surgeon General.

§ 61.8 Benefits: Stipends; dependency allowances; travel allowances; vacation.

Individuals awarded regular fellowships shall be entitled to such of the following benefits as are authorized for the particular series of fellowship:

(a) Stipend.

(b) Dependency allowances.

(c) When authorized in advance, separate allowances for travel. Such allowances may not exceed amounts prescribed by the Surgeon General for

(1) Travel to the place where the fellow is to be located during the fellowship term, and

(2) Travel to return the fellow at the end of the fellowship term to his home or other place he left to carry out the fellowship, provided that (unless otherwise prescribed by the Surgeon General) such return travel is to or from a place outside the continental United States.

No allowances will be granted for shipping personal effects or household goods and no allowances will be granted for transporting dependents, except as authorized by the Surgeon General for travel undertaken by dependents (spouse and/or dependent children only) to or from a place outside the continental United States where the fellow is to be located during the fellowship term and for return from such place or except as otherwise prescribed by the Surgeon General for a particular series of fellowships.

(d) Vacation. Stipends and allowances will not be increased, or be paid beyond the term of a fellowship, on account of vacation an individual might have been entitled to but did not take.

§ 61.9 Payments: Stipends; dependency allowances; travel allowances.

Payments for stipends, dependency allowances, and the travel allowances specified in § 61.8 may be made directly to the fellow or to the sponsoring institution for payment to the fellow.

§ 61.10 Benefits: Tuition and other expenses.

The Surgeon General may authorize allowances for payment of expenses, in whole or in part, of tuition, fees, equipment, supplies, attendance at meetings required to carry out the purposes of

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the fellowship, or other expenses of the activities of the fellow.

§61.11 Payments: Tuition and other expenses.

(a) *Tuition and fees.* Allowances for tuition and fees may be made to the fellow or sponsoring institution.

(b) *Other expenses; standard or maximum allowances.* Any allowances for equipment, supplies, attendance at meetings, and other expenses shall, except as may otherwise be prescribed herein or by the Surgeon General, be paid to the sponsoring institution. The Surgeon General may establish a standard allowance or a maximum allowance for payment to the sponsoring institution for such expenses.

(c) *Attendance at meetings—fellows sponsored by Federal agencies.* Allowances for expenses of attendance at meetings by fellows who are sponsored by Federal agencies may be paid directly to such fellows.

(d) *Installments.* Payments to sponsoring institutions and to fellows under this section or under §61.9 may be made in advance or by way of reimbursement and, except as may otherwise be prescribed by the Surgeon General, in monthly installments.

§61.12 Accountability.

Payments shall be subject to such requirements relating to accountability as may be specified by the Surgeon General.

§61.13 Duration and continuation.

An award period may be any period not in excess of 2 years. The Surgeon General may make one or more continuation awards for an additional period upon a finding of satisfactory progress toward accomplishment of the purposes of the initial fellowship award. Additional support may be provided on appropriate justification after expiration of the period of support involved in the previous award.

§61.14 Separate consideration of information concerning moral character or loyalty.

No information in the records or possession of the Public Health Service concerning the moral character or loyalty of a fellow will be made available

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to any fellowship committee involved in recommending appointments of fellows.

§61.15 Moral character or loyalty; reference to Special Review Committee; review and recommendation.

(a) *Moral character or loyalty; reference to Special Review Committee.* Whenever the Surgeon General has substantial evidence with respect to any fellow (1) that the statement filed pursuant to §61.5(d) was not made in good faith; or (2) that a fellow has (i) been convicted of a crime involving moral turpitude or (ii) engaged in conduct involving moral turpitude (unless in the case of either paragraph (a)(2) (i) or (ii) of this section, it is established that the fellow is, nevertheless, then a person of good moral character), the Surgeon General shall refer the pertinent records to a Special Review Committee established as prescribed in paragraph (b) of this section.

(b) *Special Review Committee; composition.* The Special Review Committee shall be composed of a representative of the Office of the Surgeon General designated by the Surgeon General as chairman but nonvoting member, the appropriate Associate Director or comparable official of the bureau involved, the Chief of the Division of Research Grants, the Director of the Institute or the Chief of the Division which awarded the fellowship in question, or their delegates, and two additional members appointed by the Surgeon General.

(c) *Information; supplementation.* The Committee may supplement the information referred to it by such correspondence, personal interviews, or other informal methods as necessary in order to make its recommendation as provided in paragraph (d) of this section.

(d) *Review and recommendation.* The Committee shall review the pertinent records, determine whether there is substantial reason to believe that the award should be terminated or not continued either on grounds relating to moral character or on the ground that the statement filed pursuant to §61.5(d) was not made in good faith, and make its recommendation to the Surgeon

General in writing, with reasons therefor, accordingly.

§ 61.16 Termination of or refusal to continue award on grounds relating to moral character or loyalty; hearing.

If, after review of the recommendation of the Special Review Committee, the Surgeon General believes that the award should be terminated or should not be continued, he shall notify the fellow and sponsoring institution in writing that unless a request for a hearing is made by the fellow within 20 days after the fellow's receipt of such notice, his fellowship will be terminated or his application for continuation of the award denied. A copy of the regulations under this subpart and a copy of part 10 of title 45, Code of Federal Regulations, shall be enclosed with the notice. The notice shall set forth, as specifically as security permits, the grounds for the questions pertaining to moral character or loyalty. Any such request for a hearing shall be promptly submitted by the Surgeon General to the Chairman of the Departmental Fellowship Review Panel for handling in accordance with such part 10.

§ 61.17 Termination on grounds other than those relating to moral character or loyalty.

The Surgeon General may terminate a fellowship upon receipt from the fellow of a written request for termination. The Surgeon General shall terminate any fellowship prior to the date it would otherwise expire if he determines that the fellow's performance is unsatisfactory or that the fellow or the sponsoring institution is unfit or unable to carry out the purpose of the fellowship. The fellow and the sponsoring institution shall be notified in writing of such termination.

§ 61.18 Publications.

Publication, distribution, and disposition of all manuscripts and other materials resulting from a fellowship awarded hereunder shall be subject to the conditions that all such materials shall bear appropriate acknowledgment of Public Health Service support, that fellows shall furnish copies of such pub-

lications or other materials as may be requested by the Surgeon General, and to such other conditions as the Surgeon General may prescribe.

§ 61.19 Copyright and reproduction.

Where the work accomplished under a fellowship award results in a book or other copyrightable material, the author is free to copyright the work, but the Public Health Service reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use, and to authorize others to use, all copyrightable or copyrighted material resulting from the fellowship award.

§ 61.20 Inventions or discoveries.

Any fellowship award made hereunder is subject to the regulations of the Department of Health and Human Services set forth in title 45 CFR parts 6 and 8, as amended. Such regulations shall apply to any activity for which fellowship funds are in fact used, whether within the scope of the fellowship as approved or otherwise. Appropriate measures shall be taken by the fellow, the sponsoring institution, and the Surgeon General to assure that no contracts, assignments, or other arrangements inconsistent with the fellowship obligation are entered into or continued and that all personnel involved in the supported activity are aware of and comply with such obligation. Laboratory notes, related technical data and information pertaining to inventions or discoveries shall be maintained for such periods, and filed with or otherwise made available to the Surgeon General or those whom he may designate at such times and in such manner as he may determine necessary to comply with such Department regulations.

§ 61.21 Interest.

Any interest earned through deposit or investment by the sponsoring institution of funds paid pursuant to the provisions of this subpart shall be paid to the United States as such interest is received by the sponsoring institution.

§ 61.22 Nondiscrimination.

Attention is called to the fact that funds paid to a sponsoring institution

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pursuant to § 61.11 in order to meet the expenses of the activities of a fellow are considered Federal financial assistance to such institution. The institution is thus subject in this respect to the prohibition against discrimination on the basis of race, color, or national origin imposed by title VI, Civil Rights Act of 1964, and the implementing Regulation of the Department of Health and Human Services (45 CFR part 80).

Subpart B—Service Fellowships

AUTHORITY: 42 U.S.C. 209, 210, 216.

SOURCE: 31 FR 12098, Sept. 16, 1966, unless otherwise noted.

§ 61.30 Definitions.

As used in this part:

Continental United States does not include Hawaii or Alaska.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

Service Fellowship is one which requires the performance of services, either full or part time, for the Public Health Service.

[63 FR 9950, Feb. 27, 1998]

§ 61.31 Applicability.

The regulations in this part apply to the establishment of service fellowships in the Public Health Service, the designation of persons to receive such fellowships, and the appointment of service fellows under authority of section 207(g) of the Public Health Service Act.

§ 61.32 Purpose of service fellowships.

Service fellowships in the Public Health Service are for the purpose of encouraging and promoting research, studies, and investigations related to health. Such fellowships may be provided to secure the services of talented scientists for a period of limited duration for health-related research, studies, and investigations where the nature of the work or the character of the individual's services render customary employing methods impracticable or less effective.

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§ 61.33 Establishment of service fellowships.

All service fellowships shall be established by the Secretary. In establishing a service fellowship, or a series of service fellowships, the Secretary shall prescribe in writing the conditions (in addition to those provided in the regulations in this part) under which service fellows will be appointed and will hold their fellowships.

[63 FR 9950, Feb. 27, 1998]

§ 61.34 Qualifications.

Scholastic and other qualifications shall be prescribed by the Secretary for each service fellowship, or series of service fellowships. Each individual appointed to a service fellowship shall:

(a) Have presented satisfactory evidence of general suitability, including professional and personal fitness; and

(b) Possess any other qualifications as reasonably may be prescribed.

[63 FR 9950, Feb. 27, 1998]

§ 61.35 Method of application.

Application for a service fellowship shall be made in accordance with procedures established by the Secretary.

[63 FR 9950, Feb. 27, 1998]

§ 61.36 Selection and appointment of service fellows.

The Secretary shall:

(a) Prescribe a suitable professional and personal fitness review and an examination of the applicant's qualifications;

(b) Designate in writing persons to receive service fellowships; and

(c) Establish procedures for the appointment of service fellows.

[63 FR 9950, Feb. 27, 1998]

§ 61.37 Stipends, allowances, and benefits.

(a) *Stipends.* Service fellows shall be entitled to such stipend as is authorized by the Secretary for each service fellowship or series of service fellowships.

(b) *Travel and transportation allowances.* Under conditions prescribed by the Secretary, an individual appointed as a service fellow may be authorized

personal travel allowances or transportation and per diem, travel allowances or transportation for his or her immediate family, and transportation of household goods and personal effects, in conjunction with travel authorized by the Secretary.

(1) From place of residence, within or outside the continental United States, to first duty station,

(2) For any change of duty station ordered by the Service during the term of the fellowship, and

(3) From last duty station to the place of residence which he left to accept the fellowship, or to some other place at no greater cost to the Government.

(4) A service fellow shall be entitled to travel allowances or transportation and per diem while traveling on official business away from his or her permanent duty station during the term of the fellowship. Except as otherwise provided herein, a service fellow shall be entitled to travel and transportation allowances authorized in this part at the same rates as may be authorized by law and regulations for other civilian employees of the Public Health Service. If a service fellow dies during the term of a fellowship, and the place of residence that was left by the service fellow to accept the fellowship was outside the continental United States, the payment of expenses of preparing the remains for burial and transporting them to the place of residence for interment may be authorized. In the case of deceased service fellows whose place of residence was within the continental United States, payment of the expenses of preparing the remains and transporting them to the place of residence for interment may be authorized as provided for other civilian employees of the Public Health Service.

(c) *Benefits.* In addition to other benefits provided herein, service fellows shall be entitled to benefits as provided by law or regulation for other civilian employees of the Public Health Service.

(d) *Training.* Service fellows are eligible for training at Government expense on the same basis as other civilian employees.

[31 FR 12098, Sept. 16, 1966, as amended at 63 FR 9950, Feb. 27, 1998]

§ 61.38 Duration of service fellowships.

Initial appointments to service fellowships may be made for varying periods not in excess of 5 years. Such an appointment may be extended for varying periods not in excess of 5 years for each period in accordance with procedures and requirements established by the Secretary.

[63 FR 9951, Feb. 27, 1998]

PART 62—NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP AND LOAN REPAYMENT PROGRAMS

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AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 751 of the Public Health Service Act, 90 Stat. 2281 (42 U.S.C. 294t), unless otherwise noted.

SOURCE: 45 FR 55429, Aug. 20, 1980, unless otherwise noted.

Subpart A—National Health Service Corps Scholarship Program

§ 62.1 What is the scope and purpose of the National Health Service Corps scholarship program?

These regulations apply to the award of scholarships under the National Health Service Corps Scholarship Program authorized by section 751 of the Public Health Service Act (42 U.S.C. 294t) to students receiving academic training in medicine, osteopathy, dentistry, and other health professions. The purpose of this program is to assure an adequate supply of trained health professionals for the National Health Service Corps which is used by the Secretary to improve the delivery of health services in health manpower shortage areas.

§ 62.2 Definitions.

As used in this part:

Acceptable level of academic standing means the level at which a full-time student retains eligibility to continue in attendance in school under the school's standards and practices.

Act means the Public Health Service Act, as amended.

Approved graduate training means those programs of graduate training in medicine, osteopathy, dentistry or other health professions which (a) lead to eligibility for board certification or which provide other evidence of completion, and (b) have been approved by the appropriate health professions body as determined by the Secretary.

Full-time student means an individual pursuing a course of study leading to a degree in medicine, osteopathy, dentistry or an equivalent credential for a particular health profession who is enrolled for a sufficient number of credit hours in any academic term to complete the course of study within not more than the number of academic terms normally required at the school.

If an individual is enrolled in a school and is pursuing a course of study which is designed to be completed in more than 4 years, the individual will be considered a full-time student for only the last 4 years of the course of study.

Health manpower shortage area means the geographic area, the population group, the public or nonprofit private medical facility, or other public facility which has been determined by the Secretary to have a shortage of health manpower under section 332 of the Act and its implementing regulations (42 CFR part 5).

National of the United States means a citizen of the United States or a person who, though not a citizen of the United States, owes permanent allegiance to the United States.

Public Health and National Health Service Corps Scholarship Training Program, or *PH/NHSC Scholarship Training Program*, means the program authorized by section 225 of the Act as in effect on September 30, 1977, and repealed on October 1, 1977.

Scholarship Program means the National Health Service Corps Scholarship Program authorized by section 751 of the Act (42 U.S.C. 294t).

Scholarship Program participant or *participant* means an individual whose application to the Scholarship Program has been approved and whose contract has been accepted and signed by the Secretary.

School means a school of medicine, osteopathy, dentistry, or other health profession which (a) provides training leading to a degree of doctor of medicine, doctor of osteopathy, doctor of dentistry, or an equivalent credential for a particular health profession, and (b) which is accredited by a body or bodies recognized for accreditation purposes by the Secretary of Education.

School year means all or part of the 12-month period from July 1 through June 30 during which an applicant is enrolled in a school as a full-time student.

Service means the United States Public Health Service.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved

has been delegated.

State means one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 62.3 Who is eligible to apply for a scholarship program award?

(a) To be eligible for a scholarship under this part an applicant must:

(1) Be accepted for enrollment, or be enrolled, as a full-time student in a school located in a State;

(2) Be pursuing a course of study or program offered by the school leading to a degree in medicine, osteopathy, dentistry, or an equivalent credential for a particular health profession;

(3) Be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the National Health Service Corps;

(4) Be a National of the United States; and

(5) Submit an application to participate in the Scholarship Program together with a signed contract as described in section 751(f) of the Act.

(b) Any applicant who owes an obligation for professional practice to a State or other entity under an agreement entered into before filing an application under this part is ineligible for an award unless a written statement satisfactory to the Secretary is submitted from the State or entity that (1) there is no potential conflict in fulfilling the service obligation to the State or entity and the Scholarship Program, and that (2) the Scholarship Program service obligation will be served before the service obligation for professional practice owed to the State or entity.

(c) Any individual who receives a scholarship under the Indian Health Service Scholarship Program (section 757 of the Act) or the Scholarship Program for First-Year Students of Exceptional Financial Need (section 758 of the Act) is ineligible to participate in the Scholarship Program during the

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School year(s) for which the scholarships under sections 757 or 758 of the Act were awarded.

§ 62.4 To whom will scholarship program awards be available in addition to those individuals pursuing courses of study leading to degrees in medicine, osteopathy, or dentistry?

The Secretary will, from time-to-time, publish in the FEDERAL REGISTER a list of those health professions in addition to medicine, osteopathy, and dentistry for which the National Health Service Corps has need and for which support is available. The Secretary will also publish any other eligibility criteria, in addition to those in § 62.3, that may be required to assure that participants can be utilized during their periods of obligated service in a manner that will best meet the needs of the National Health Service Corps.

§ 62.5 How is application made for a scholarship program award?

Each individual desiring a scholarship under this part must submit an application (including a signed contract as required under section 751(f) of the Act) in the form and at the time prescribed by the Secretary.

§ 62.6 How will individuals be selected to participate in the scholarship program?

(a) *General.* In deciding which applications for participation in the Scholarship Program will be approved, the Secretary will place the applications into categories based upon the selection priorities described in paragraph (b) of this section. Except for continuation awards (see paragraph (e) of this section) the Secretary will then evaluate each applicant under paragraph (c) of this section.

(b) *Priorities.* (1) First priority will be given to individuals who have previously received a scholarship under the PH/NHSC Scholarship Training Program, a scholarship under this Scholarship Program, or a scholarship under section 758 of the Act, authorizing scholarships for first-year students of exceptional financial need. (2) Second priority will be given to applicants who are entering their first year of study.

(c) *Selection.* (1) In selecting participants, the Secretary will take into consideration those factors which he or she determines necessary to assure effective participation in the Scholarship Program. These factors may include, but not be limited to (i) work experience, (ii) community background, (iii) career goals, (iv) faculty recommendation, and (v) academic performance.

(2) Special consideration will be given to (i) medical and osteopathic students who indicate their intention to enter family practice, internal medicine, pediatrics, or osteopathic general practice residencies, (ii) dental students who indicate their intention to undertake general practice training following graduation or who plan no postgraduate training, and (iii) those individuals who indicate an intent to pursue other types of clinical practice or specialized training for which the National Health Service Corps has a particular need.

(d) *Duration of Scholarship award.* Subject to the availability of funds for the Scholarship Program, the Secretary will award a participant a scholarship under this part for a period of 1 school year.

(e) *Continuation awards.* Subject to the availability of funds for the Scholarship Program, the Secretary will award a continuation scholarship if (1) the participant requests a continuation, (2) the award will not extend the total period of Scholarship Program support beyond 4 years, and (3) the participant is eligible for continued participation in the Scholarship Program.

§ 62.7 What will an individual be awarded for participating in the scholarship program?

(a) *Amount of scholarship.* (1) A scholarship award for each school year will consist of (i) tuition, (ii) reasonable educational expenses, including required fees, books, supplies, and required educational equipment, and (iii) a monthly stipend for the 12-month period beginning with the first month of each school year in which the individual is a participant. For purposes of this section “required fees” means those fees which are charged by the school to all students pursuing a similar curriculum and “required educational

equipment” means educational equipment which must be rented or purchased by all students pursuing a similar curriculum at that school.

(2) The Secretary may enter into a contract with the school in which the participant is enrolled for the direct payment of tuition and reasonable educational expenses in the participant's behalf.

(b) *Payment of scholarship: Leave-of-absence; repeated course work.* The Secretary will suspend scholarship payments to or on behalf of a participant if the school (1) approves a leave-of-absence for the participant for health, personal, or other reasons, or (2) requires the participant to repeat course work for which the Secretary has previously made scholarship payments under § 62.7. However, if the repeated course work does not delay the participant's graduation date, scholarship payments will continue except for any additional costs relating to the repeated course work. Any scholarship payments suspended under this paragraph will be resumed by the Secretary upon notification by the school that the participant has returned from the leave-of-absence or has completed the repeated course work and is pursuing as a full-time student the course of study for which the scholarship was awarded.

§ 62.8 What does an individual have to do in return for the scholarship program award?

(a) *General.* Except as provided in paragraphs (d), (f), and (g) of this section, each participant is obligated to (1) become a member of the National Health Service Corps employed as a Commissioned Officer in the Regular or Reserve Corps of the Service or as a Federal civilian in the full-time clinical practice of the participant's profession and (2) serve in the health manpower shortage area to which the participant is assigned by the National Health Service Corps.

(b) *Beginning of service.* (1) The period of obligated service will begin when the Scholarship Program participant begins to provide services in the health manpower shortage area to which he or she is assigned by the Secretary. Except for those participants who receive

a deferral under § 62.9 (a) or (b), this assignment will be made by the Secretary as soon as possible following: (i) the completion of the participant's course of study leading to a degree in medicine, osteopathy, dentistry, or an equivalent credential for a particular health profession, and (ii) appointment of the participant as a Commissioned Officer in the Regular or Reserve Corps of the Service or as a civilian member of the National Health Service Corps.

(2) For purposes of this paragraph, “appointment” means only those appointments as Commissioned Officers in the Regular or Reserve Corps of the Service or as civilian members of the National Health Service Corps made specifically for the purpose of serving a participant's period of obligated service.

(c) *Duration of service.* Except as provided in § 62.14(b)(1), the period for which the Scholarship Program participant is obligated to serve is equal to 1 year for each school year for which the participant receives a scholarship award under this part, or 2 years, whichever is greater.

(d) *Service by detail.* If the Secretary determines that there is no need in a health manpower shortage area for a member of the profession in which the Scholarship Program participant is obligated to provide service, the Scholarship Program participant may be detailed to serve the period of obligated service as a full-time member of the profession for which the participant has been trained, in any unit of the Department of Health and Human Services as the Secretary may determine.

(e) *Creditability of approved graduate training.* Except as provided in § 62.14(b)(2), no period of approved graduate training will be credited toward satisfying the period of obligated service incurred under the Scholarship Program.

(f) *Service under the National Research Service Award Program.* (1) A Scholarship Program participant who demonstrates exceptional promise for medical research may perform the period of obligated service owed under this section by participating in the National Research Service Award Program for individual postdoctoral fellows authorized under section 472 of the Act.

(2) Exceptional promise for medical research will be demonstrated if the participant applies for a National Research Service Award for individual postdoctoral fellows, is selected to participate in this research program, and accepts the offer of participation. A Scholarship Program participant in the National Research Service Award Program will receive credit toward satisfying the period of obligated service incurred under this section for any period of time he or she is engaged in activities which meet the service requirements of the National Research Service Award Program.

(3) If the time served under the National Research Service Award Program is less than the total period of obligated service owed under the Scholarship Program, the participant will serve the remainder of the Scholarship Program service obligation (i) in activities which meet the criteria for service under the National Research Service Award Program, as approved by the Secretary or (ii) as a member of the National Health Service Corps providing health services in the full-time clinical practice of his or her health profession. A participant who fails to begin or complete the service requirements under the National Research Service Award Program may be subject to the default penalty under § 62.10(c) of this part and the default penalties under the National Research Service Award Program.

(g) *Release from service obligation to engage in private practice.* The Secretary will release a participant from all or part of the service obligation if the participant applies for a release under section 753 of the Act and agrees in writing to engage for a period equal to the remaining period of the participant's service obligation in the full-time private clinical practice of the participant's health profession, under the requirements of section 753 of the Act.

§ 62.9 Under what circumstances can the period of obligated service be deferred to complete approved graduate training?

(a) *Requested deferment.* Upon the request of any participant receiving a degree from a school of medicine, osteop-

athy, or dentistry, veterinary medicine, optometry, podiatry or pharmacy, the Secretary will defer the beginning date of the obligated service to allow the participant to complete an approved graduate training program. The period of this deferment may not exceed (1) three years for any participant receiving a degree from a school of medicine, osteopathy or dentistry, or (2) one year for any participant receiving a degree from a school of veterinary medicine, optometry, podiatry or pharmacy. The Secretary may, however, extend this period of deferment if the Secretary determines that the extension is consistent with the needs of the National Health Service Corps.

(b) *Required deferment.* Each participant receiving a degree in medicine or osteopathy who does not intend to enter training which can be completed within the deferment period granted under paragraph (a) of this section must complete at least one year of approved graduate training before beginning the period of obligated service. This one year of training must be in (1) an allopathic flexible first-year program whose sponsorship includes approved residencies in family practice, internal medicine, pediatrics, or a categorical first-year program in family practice, internal medicine, or pediatrics; (2) a rotating internship in osteopathic medicine; or (3) such other programs as the Secretary determines provides comparable experience. Any participant receiving a degree in medicine or osteopathy who fails to complete the one year of required training or an approved graduate training program for which a deferment was granted under paragraph (a) of this section will be subject to the default penalties of § 62.10(c).

(c) *Altering deferment.* Before altering the length or type of approved graduate training for which the period of obligated service was deferred under paragraphs (a) or (b) of this section, the participant must request and obtain the Secretary's approval of the alteration.

(d) *Additional terms of deferment.* The Secretary may prescribe additional terms and conditions for deferment under paragraphs (a), (b), and (c) of this

section as necessary to carry out the purposes of the Scholarship Program.

(e) *Beginning of service after deferment.* Any participant whose period of obligated service has been deferred under paragraphs (a) or (b) of this section must begin the obligated service when the participant begins to provide health services in the health manpower shortage area to which he or she is assigned by the Secretary. This assignment will be made by the Secretary as soon as possible following (1) the completion of the requested or required graduate training for which the deferment was granted, and (2) appointment as a Commissioned Officer in the Regular or Reserve Corps of the Service or as a civilian member of the National Health Service Corps.

§ 62.10 What will happen if an individual does not comply with the terms and conditions of participating in the scholarship program?

(a) If a participant, other than one described in paragraph (b) of this section, fails to accept payment or instructs the school not to accept payment of the scholarship provided by the Secretary, the participant must, in addition to any service or other obligation incurred under the contract, pay to the United States the amount of \$1,500 liquidated damages. Payment of this amount must be made within 30 days of the date on which the participant fails to accept payment of the scholarship award or instructs the school not to accept payment.

(b) When a participant fails to maintain an acceptable level of academic standing, is dismissed from the school for disciplinary reasons, or voluntarily terminates the course of study or program for which the scholarship was awarded before completing the course of study or program, the participant must, instead of performing any service obligation, pay to the United States an amount equal to all scholarship funds awarded under § 62.7. Payment of this amount must be made within 3 years of the date the participant becomes liable to make payment under this paragraph.

(c) If a participant fails to begin or complete the period of obligated service incurred under § 62.8, including fail-

ing to comply with the applicable terms and conditions of a deferment granted by the Secretary, the participant must pay to the United States an amount determined by the formula set forth in section 754(c) of the Act. Payment of this amount shall be made within 1 year of the date that the participant failed to begin or complete the period of obligated service, as determined by the Secretary.

§ 62.11 When can a scholarship program payment obligation be discharged in bankruptcy?

In accordance with section 754(d)(3) of the Act, any payment obligation incurred under § 62.10 may not be discharged in bankruptcy under title XI of the United States Code until 5 years after the date on which the payment obligation is due.

§ 62.12 Under what circumstances can the service or payment obligation be canceled, waived or suspended?

(a) Any obligation of a participant for service or payment will be canceled upon the death of the participant.

(b)(1) A participation may seek a waiver or suspension of the service or payment obligations incurred under this part by written request to the Secretary setting forth the bases, circumstances, and causes which support the requested action. The Secretary may approve a request for a suspension for a period of 1 year. A renewal of this suspension may also be granted.

(2) The Secretary may waive or suspend any service or payment obligation incurred by a participant whenever compliance by the participant (i) is impossible, or (ii) would involve extreme hardship to the participant and if enforcement of the service or payment obligation would be against equity and good conscience.

(c) Compliance by a participant with a service or payment obligation will be considered impossible if the Secretary determines, on the basis of information and documentation as may be required, that the participant suffers from a physical or mental disability resulting in the permanent inability of the participant to perform the service or other activities which would be necessary to comply with the obligation.

(d) In determining whether to waive or suspend any or all of the service or payment obligations of a participant as imposing an undue hardship and being against equity and good conscience, the Secretary, on the basis of information and documentation as may be required, will consider:

(1) The participant's present financial resources and obligations;

(2) The participant's estimated future financial resources and obligations; and

(3) The extent to which the participant has problems of a personal nature, such as physical or mental disability, terminal illness in the immediate family which so intrude on the participant's present and future ability to perform as to raise a presumption that the individual will be unable to perform the obligation incurred.

§ 62.13 What are the limitations on the receipt of concurrent benefits?

Under section 741(f) or 836(h) of the Act, the Secretary may agree to repay a portion of an individual's educational loans in return for the individual's agreement to practice his or her profession in an area in need of health manpower. However, a Scholarship Program participant may not enter into an agreement with the Secretary under section 741(f) or 836(h) of the Act, until either:

(a) The participant has completed the service obligation under the Scholarship Program,

(b) The Secretary has recovered from the participant an amount determined under § 62.10, or

(c) Any service or payment obligation has been waived under § 62.12.

In no case shall a scholarship received under these regulations be considered an educational loan for the purposes of section 741(f) or 836(h) of the Act.

§ 62.14 What are the special provisions relating to recipients of awards under the PH/NHSC scholarship training program who will also receive awards under the scholarship program?

(a) Except as provided in paragraph (b) of this section, if a participant has previously received an award under the PH/NHSC Scholarship Training Pro-

gram and also receives an award under the Scholarship Program, the terms and conditions of these regulations will apply to the participant's entire obligation incurred under both the PH/NHSC Scholarship Training Program and the Scholarship Program.

(b) If a participant has received an award under the PH/NHSC Scholarship Training Program and also receives an award under the Scholarship Program, the following conditions apply:

(1) *Period of obligated service—carry over.* The period of obligated service owed by the participant is equal to the total number of school years for which scholarship support was awarded under both the PH/NHSC Scholarship Training Program and the Scholarship Program without regard to either Program's minimum support requirement under 42 CFR 62.7(a) (1976) as adopted on May 22, 1974 (see 39 FR 17962), and under § 62.8(c) of this part.

(2) *Credit for internship and residency training.* (i) If a participant received a scholarship under the PH/NHSC Scholarship Training Program for any school year beginning before October 12, 1976, the participant will receive credit toward satisfying the periods of obligated service incurred under the PH/NHSC Scholarship Training Program and under § 62.8 of this part for any periods of internship or residency training served in a Service or National Health Service Corps facility.

(ii) If a participant received a scholarship for the first time during the 1977–78 school year under the PH/NHSC Scholarship Training Program, the participant will only receive 1 year of credit toward satisfying the period of obligated service incurred under the PH/NHSC Scholarship Training Program for internship or residency training served in a Service or National Health Service Corps facility.

(3) *Default penalties.* The PH/NHSC Scholarship Training Program default penalty will apply to a participant who fails to begin or complete the active duty service obligation incurred under that Program, and the § 62.10 default penalties will apply to a participant who fails to begin or complete the service obligation incurred under § 62.8 of these regulations. In determining which default penalty to apply when an

individual who has received a Scholarship award under both the PH/NHSC Scholarship Training Program and the Scholarship Program fails to begin or complete his service obligation, the service obligations will be considered to have been served in the order in which they were incurred.

Subpart B—National Health Service Corps Loan Repayment Program

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 338B of the Public Health Service Act, 101 Stat. 992 (42 U.S.C. 2541-1).

SOURCE: 54 FR 13462, Apr. 3, 1989, unless otherwise noted.

§ 62.21 What is the scope and purpose of the National Health Service Corps Loan Repayment Program?

The regulations of this subpart apply to the award of health professions educational loan payments under the National Health Service Corps Loan Repayment Program authorized by section 338B of the Public Health Service Act (42 U.S.C. 2541-1). The purpose of the Program is to assure an adequate supply of trained health professionals for the National Health Service Corps. These professionals will be assigned by the Secretary to provide necessary health services to persons living in designated health manpower shortage areas.

§ 62.22 Definitions.

The definitions in § 62.2 of this part will apply for the purpose of this subpart, except for the definition of *approved graduate training*. The following definitions will also apply for purposes of this subpart:

Approved graduate training means a program of graduate training in allopathic or osteopathic medicine, dentistry or other health profession which (a) leads to eligibility for board certification or which provides other evidence of completion, (b) has been approved by the appropriate health professions body as determined by the Secretary and (c) is in the specialty or type of training specified by the Program participant in the Loan Repay-

ment Program Contract or, at the Program participant's request and at the Secretary's option, is in a specialty or area of training determined by the Secretary to be consistent with the needs of the National Health Service Corps.

Commercial loans means loans made by banks, credit unions, savings and loan associations, insurance companies, schools, and other financial or credit institutions which are subject to examination and supervision in their capacity as lenders by an agency of the United States or of the State in which the lender has its principal place of business.

Educational expenses means the costs of the health professions education, exclusive of the tuition, such as fees, books, supplies, and educational equipment and materials.

Government loans means loans which are made by Federal, State, county or city agencies which are authorized by law to make such loans.

Living expenses means the costs of room and board, transportation and commuting costs and other costs incurred during an individual's attendance at a health professions school.

Loan Repayment Program means the National Health Service Corps Loan Repayment Program authorized by section 338B of the Act (42 U.S.C. 2541-1).

Loan Repayment Program Contract means the agreement, which is signed by an applicant and the Secretary, for the Loan Repayment Program wherein the applicant agrees to accept repayment of health professions educational loans and to serve in accordance with the provisions of section 338B of the Act and this subpart for a prescribed period of obligated service.

Medically underserved area means *health manpower shortage area* as defined in § 62.2.

Program participant means an individual whose application to the Loan Repayment Program has been approved and whose contract has been accepted and signed by the Secretary.

Qualifying loans means government and commercial loans for actual costs paid for tuition, reasonable educational expenses, and reasonable living expenses relating to the obtainment of a degree in allopathic or osteopathic medicine, dentistry, or other health

profession. Such loans must have documentation which is contemporaneous with the training received in a health professions school. If health professions educational loans are refinanced, the original documentation of the loan(s) will be required to be submitted to the Secretary to establish the contemporaneous nature of such loans.

Reasonable educational and living expenses means those educational and living expenses which are equal to or less than the sum of the school's estimated standard student budgets for educational and living expenses for the degree program and for the year(s) during which the Program participant is/was enrolled in the school. However, if the school attended by the Program participant does/did not have a standard student budget or if a Program participant requests repayment for educational and living expenses which are in excess of the standard student budgets described in the preceding sentence, the Program participant must submit documentation, as required by the Secretary, to substantiate the reasonableness of all educational and living expenses incurred by the Program participant. To the extent that the Secretary determines, upon review of the Program participant's documentation, that all or a portion of the educational and living expenses are reasonable, these expenses will qualify for repayment.

§ 62.23 How will individuals be selected to participate in the Loan Repayment Program?

(a) In determining which applications from eligible individuals for participation in the Loan Repayment Program will be accepted for consideration, the Secretary will apply the following criteria:

- (1) The extent to which an individual's training is in a health profession or specialty determined by the Secretary to be needed by the National Health Service Corps;
- (2) The individual's commitment to serve in medically underserved areas;
- (3) The availability of the individual for service, with highest consideration being given to individuals who will be available for service at the earliest dates;

(4) The length of the individual's proposed service obligation, with greatest consideration being given to persons who agree to serve for longer periods of time; and

(5) The individual's academic standing, prior professional experience in a health manpower shortage area, board certification, residency achievements, peer recommendations, depth of past residency practice experience and other criteria related to professional competence or conduct.

(b) Among qualified applicants, the Secretary will give priority to applications from individuals whose health professions or specialties are most needed by the NHSC and who are, in the Secretary's judgement, most committed to practice in medically underserved areas.

(c) By notice published in the FEDERAL REGISTER from time to time, the Secretary will specify the professions and specialties most needed by the National Health Service Corps.

§ 62.24 Who is eligible to apply for the Loan Repayment Program?

(a) To be eligible to participate in the Loan Repayment Program an individual must:

(1)(i) Be enrolled as a full-time student in the final year of a course of study or program approved by the Secretary which leads to a degree in allopathic or osteopathic medicine, dentistry or other health profession and which is offered by an accredited school in a State or

(ii) Be enrolled in an approved graduate training program in allopathic or osteopathic medicine or dentistry or other health profession in a State, or

(iii) Have a degree in allopathic or osteopathic medicine or dentistry or other health profession and have completed an approved graduate training program in a State (or received a waiver of the completion requirement under § 62.26(d) of this subpart) and have a current and valid license to practice such health profession in a State;

(2) Be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Public Health Service or be eligible for selection for civilian service in the National Health Service Corps;

(3) Submit an application to participate in the Loan Repayment Program; and

(4) Sign and submit to the Secretary, at the time of the submission of such application, a written contract agreeing to accept repayment of health professions educational loans and to serve (in accordance with this subpart) for the applicable period of obligated service in a health manpower shortage area as determined by the Secretary.

(b) Any individual who owes an obligation for health professional service to the Federal Government or a State or other entity under an agreement with such Federal, State or other entity is ineligible for the Loan Repayment Program unless such obligation will be completely satisfied prior to the beginning of service under this Program.

(c) Individuals in breach of a written contract entered into under section 338A of the Act and liable to the United States under section 338E(b) of the Act, in breach of a written contract entered into under section 225 of the Act (as in effect on September 30, 1977) and liable to the United States under section 225(f)(1) of the Act (as in effect on September 30, 1977) or in breach of any other obligation for health professional service to a Federal, State or local government entity are not eligible for participation in the Loan Repayment Program.

(Approved by the Office of Management and Budget under control number 0915-0127)

§ 62.25 What does the Loan Repayment Program provide?

(a) *Loan repayment.* For each year of service the individual agrees to serve, with a minimum of 2 years of obligated service, the Secretary may pay:

(1) Except as provided in paragraph (a)(2) of this section, up to \$20,000 per year of a Program participant's qualifying loans or

(2) Up to \$25,000 per year for a Program participant's qualifying loans if the Program participant agrees to provide obligated service in the Indian Health Service or a health facility or program operated by a tribe or tribal organization under the Indian Self-Determination Act.

The Secretary may establish different levels of annual loan repayment to en-

courage Program participants to serve in a manner which is in the best interest of the Loan Repayment Program. No loan repayments will be made for any professional practice performed prior to the effective date of the Loan Repayment Program Contract. Once a loan repayment contract has been signed by both parties, the Secretary will obligate such funds as will be necessary to ensure that sufficient funds will be available to make loan repayments for the duration of the period of obligated service.

(b) *Site visit.* The Secretary may reimburse an individual for the actual and reasonable travel expenses associated with one trip from the individual's residence to a site for the purpose of evaluating such site for service under the Loan Repayment Program.

(c) *Tax liability payments.* The Secretary may, upon a Program participant's written request, make payments in a reasonable amount, as determined by the Secretary, to reimburse the Program participant for all or part of the increased Federal, State and local tax liability resulting from loan repayments received under the Loan Repayment Program. To maximize the Federal resources available for placing participants in HMSAs, supplementary payments for increased tax liability will only be made under unusual circumstances, and in no cases will these tax liability payments exceed 20% of the annual amounts of the loans being repaid. Program participants wishing to receive tax liability payments must submit their requests for such payments in a manner prescribed by the Secretary and must provide the Secretary with any documentation the Secretary determines is necessary to establish a Program participant's increased tax liability. The Secretary will determine, based on the availability of funds and such other factors as the Secretary determines, the amounts of any such payments that may be made.

(Information collection requirements contained in paragraph (c) were approved by the Office of Management and Budget under control number 0915-0131)

[54 FR 13462, Apr. 3, 1989, as amended at 57 FR 56996, Dec. 2, 1992]

§ 62.26 What does an individual have to do in return for loan repayments received under the Loan Repayment Program?

(a) A Program participant whose eligibility for the Loan Repayment Program is based on § 62.24(a)(1)(i) of this subpart must maintain full-time enrollment, at an acceptable level of academic standing, in that course of study until its completion. Upon completion of that course of study, a Program participant who received a degree in allopathic or osteopathic medicine must enter approved graduate training and a Program participant who received a degree in a health profession other than allopathic or osteopathic medicine may enter approved graduate training. Once a Program participant enters approved graduate training, he or she must also meet the requirements set forth in paragraphs (b) (1), (2), (3), and (4) of this section. If a Program participant who received a degree in a health profession other than allopathic or osteopathic medicine does not enter approved graduate training; service, in accordance with paragraph (e) of this section, must commence as soon as possible upon the Program participant's completion of the course of study leading to his or her health professions degree.

(b) A Program participant whose eligibility for the Loan Repayment Program is based on § 62.24(a)(1)(ii) of this subpart must: (1) Continue in his or her approved graduate training program at an acceptable level of academic standing; (2) provide the Secretary with annual documentation of continued participation in that approved graduate training program at an acceptable level of academic standing; (3) successfully complete that approved graduate training program; and (4) commence service, in accordance with paragraph (e) of this section, as soon as possible upon completion of approved graduate training.

(c) A Program participant whose eligibility for the Loan Repayment Program is based on § 62.24(a)(1)(iii) of this subpart must commence service, in accordance with paragraph (e) of this section, as soon as possible after the effective date of the Loan Repayment Program Contract.

(d) If a Program participant fails to complete approved graduate training, the Secretary may, on his or her own initiative or at the Program participant's request, waive, for good cause, the completion requirement. Good cause will be deemed to exist if the Secretary determines that the Program participant has sufficient health professions training to be utilized by and make a substantial contribution to the National Health Service Corps. If waiver of the completion requirement in paragraph (b) of this section is granted; service, in accordance with paragraph (e) of this section, must commence as soon as possible after the granting of the waiver.

(e) Except for Program participants who fail to complete their course of study leading to a health professions degree or who fail to complete approved graduate training and do not receive a waiver pursuant to paragraph (d) of this section, each program participant must:

(1) Serve in a health manpower shortage area to which he or she is assigned by the Secretary as a member of the National Health Service Corps or serve pursuant to section 338D of the Act in a health manpower shortage area selected by the Secretary and

(2) Accept employment in a full-time clinical practice of the Program participant's profession, as

(i) A commissioned officer in the Regular or Reserve Corps of the Public Health Service,

(ii) A civilian member of the National Health Service Corps who is an employee of the United States,

(iii) A member of the National Health Service Corps who is not an employee of the United States, or

(iv) A private practitioner who is providing obligated service under the provisions of section 338D of the Act.

(f) The minimum length of obligated service is two years, or such longer period as the Program participant may agree to. The maximum length of obligated service is four years. If a Program participant agrees to an original contract of two or three years, such contract may be extended, subject to the availability of appropriated funding, for one year or two years (up to the four-year maximum). A one-year

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extension will not reactivate the statutory minimum requirement of two years of service.

(Information collection requirements contained in paragraph (b)(2) were approved by the Office of Management and Budget under control number 0915-0131)

§ 62.27 What will happen if an individual does not comply with the terms and conditions of participation in the Loan Repayment Program?

Program participants who default on their Loan Repayment Program Contracts will be subject to the applicable monetary payment provisions set forth at section 338E of the Act. Payment of any amount owed under section 338E of the Act shall be made within one year of the date the participant breached his or her Loan Repayment Contract, as determined by the Secretary.

§ 62.28 Under what circumstances can the service or payment obligation be canceled, waived or suspended?

A service or payment obligation under the Loan Repayment Program will be canceled or may be waived or suspended as provided in § 62.12 of this part of the regulations.

§ 62.29 Under what circumstances can the Loan Repayment Program obligation be discharged in bankruptcy?

Any payment obligation incurred under § 62.27 of this subpart may be released by a discharge in bankruptcy under title 11 of the United States Code only if such discharge is granted after the expiration of the five-year period beginning on the first date that payment was required, and only if the bankruptcy court finds that nondischarge of the obligation would be unconscionable.

§ 62.30 What other regulations and statutes apply?

Other regulations and statutes which apply to this subpart include but are not limited to:

Debt Collection Act of 1982, Pub. L. 97-365 (5 U.S.C. 5514) including Section 4, Requirement that Applicant Furnish Taxpayer Identifying Number;
Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*);

Privacy Act of 1974 (5 U.S.C. 552a);

Section 215(a) of the Public Health Service Act, as amended (42 U.S.C. 216(a)), for PHS commissioned officers, and 5 U.S.C. 3301 for civil service employees both of which authorize verification of an individual's suitability for employment;

Privacy Act of 1974; Alteration of System of Records, 52 FR 21622-21627, June 8, 1987, regarding the collection, maintenance and allowable use of personal information requested from program applicants.

Subpart C—Grants for State Loan Repayment Programs

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 338H of the Public Health Service Act, 101 Stat. 999 (42 U.S.C. 254q-1).

SOURCE: 54 FR 13464, Apr. 3, 1989, unless otherwise noted.

§ 62.51 What is the scope and purpose of the State Loan Repayment Program?

The regulations of this subpart apply to the award of grants authorized by section 338H of the Public Health Service Act (42 U.S.C. 254q-1) to support the establishment of State programs similar to the National Health Service Corps Loan Repayment Program authorized by section 338B of the Public Health Service Act (42 U.S.C. 2541-1). The purpose of this program is to improve the delivery of health services in medically underserved areas.

§ 62.52 Definitions.

In addition to the definitions in § 62.2 of this part, the following definitions will apply for purposes of this subpart:

The definitions of *Qualifying loans*, *Commercial loans*, *Government loans*, *Educational expenses*, and *Living expenses* as contained in § 62.22 of this part will apply for purposes of this subpart.

Medically underserved area means *health manpower shortage area* or an area which has been designated by a State pursuant to standards described in § 62.54(b)(1) of this subpart which the Secretary has deemed acceptable.

State Loan Repayment Program or *program* means a State loan repayment program authorized under section 338H (42 U.S.C. 254q-1) of the Act.

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§ 62.53 Who is eligible for this program?

Any State is eligible to apply for a grant under this subpart.

§ 62.54 What must applications for the State Loan Repayment Program contain?

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary requires.

(b) The application shall contain a budget and narrative statement describing the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart. In addition, applications must include:

(1) A description of the State's standards for the designation of medically underserved areas, except that no description of designation standards will be required if the State elects to use health manpower shortage areas designated by the Secretary;

(2) An assessment of the need and demand in medically underserved areas within the State for health professions manpower with special emphasis on individuals whose training is in a health profession or specialty identified by the Secretary pursuant to § 62.23(b) of this part. This assessment should include such demographic indicators of the need as the economic accessibility of health care services in the State as measured by poverty levels, the percentage of the service area population without health insurance, and the health status of the population as measured by the rates of infant mortality, low birth weight, geographic barriers and other indicators;

(3) A proposal for the placement of the health profession providers in medically underserved areas with the greatest need and demand in accordance with the need/demand assessment completed in compliance with paragraph (b)(2) of this section;

(4) Adequate assurances that sufficient current year State funds are available to cover the non-Federal share of State Loan Repayment Program costs;

(5) A description of how the program would meet the requirements of § 62.55

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to demonstrate its similarity to the NHSC Loan Repayment program;

(6) A description of the source of, and plans for the use of, State matching funds;

(7) A description of how the program would be coordinated with Federal, State and other organized activities within the State which relate to health manpower services and resources;

(8) Identification of the State entity and key personnel who would administer the grant and a description of the qualifications and experience of that entity and its personnel concerning the State's health service delivery system and health manpower needs;

(9) A description of the State's plans for administration of the State's Loan Repayment Program which may include such provisions as annual levels of loan repayment to be made under the program, the number of health professionals to be funded, the frequency and timing of the loan repayments, program incentives for longer periods of service, procedures for monitoring the service of program participants and placing professionals in default for failure to complete their service obligation, penalties for default, provisions for waivers and suspensions, and a description of the contract/obligation process to be used by the State to obligate individuals receiving State loan repayments;

(10) A description of the State's need for Federal assistance in obtaining health professions resources and demonstrated inability to obtain such resources without Federal assistance;

(11) A description of how the State will accord special consideration to medically underserved areas with large minority populations; and

(12) The signature of an individual authorized to act for the State and to assume on behalf of the State the obligations imposed by the statute, the applicable regulations of this subpart and any additional conditions of the grant.

(Approved by the Office of Management and Budget under control number 0915–0131)

§ 62.55 What State Program Elements are required to ensure similarity with the NHSC Loan Repayment Program?

A State Loan Repayment Program supported under this subpart must:

(a) Establish priorities for loan repayment applicants consistent with the provisions of § 62.23 of this part;

(b) Contract only with a person who is (1) enrolled as a full-time student in the final year of a course of study or program in an accredited school in a State leading to a degree in allopathic or osteopathic medicine, dentistry or other health profession, or (2) enrolled in an accredited graduate training program in a State in allopathic or osteopathic medicine or dentistry or other health profession, or (3) a practitioner licensed by a State who has completed training in an accredited graduate training program in allopathic or osteopathic medicine, dentistry or other health profession;

(c) Provide that health professionals participating in a State Loan Repayment Program shall:

(1) Serve for at least 2 years in a medically underserved area identified pursuant to § 62.54(b)(3) of this subpart in the full-time clinical practice of their profession,

(2) Charge for his or her professional services at the usual and customary rate prevailing in the area in which such services are provided, except that if a person is unable to pay such charge, such person shall be charged at a reduced rate or not charged any fee,

(3) In providing health services, not discriminate against any person on the basis of such person's ability to pay for such services or because payment for the health services provided to such person will be made under the insurance program established under part A or B of title XVIII of the Social Security Act or under a State plan for medical assistance approved under title XIX of such Act, and

(4) Agree to accept an assignment under section 1842(b)(3)(B)(ii) of such Act for all services for which payment may be made under part B of title XVIII of such Act and enter into an appropriate agreement with the State agency which administers the State plan for medical assistance under title

XIX of such Act to provide service to individuals entitled to medical assistance under the plan;

(d) Repay qualifying loans for participating health professionals;

(e) Provide that the loans of health professionals will be repaid on a periodic basis after the receipt of obligated services by such participant for such period; and

§ 62.56 How are the Federal grant funds and State matching funds to be used under this program?

The Federal share of any program shall not exceed 75 percent of the cost of the approved State program. The Federal share must be used to repay the qualifying loans of health professionals. No portion of the Federal share shall be used to pay for administrative costs of any State Loan Repayment Program. The State's share of the program may be used to repay qualifying loans of health professionals or administrative costs of the State's Loan Repayment Program, or a combination of both. All program administrative costs are to be borne by the State. No portion of the State's share of the program shall consist of Federal funds.

§ 62.57 How will States be selected to participate in this program?

Within the limits of funds available under section 338H of the Act, the Secretary may award grants to State applicants whose proposed Loan Repayment Programs will, in his or her judgment, best promote the purposes of section 338H of the Act, taking into account, among other pertinent factors:

(a) The need of the State for health professions manpower;

(b) The number and type of providers the State proposes to support through this program;

(c) The acceptableness of the State's standards for the designation of medically underserved areas and the appropriateness of the proposed placements of obligated providers;

(d) The degree of similarity between the proposed State Loan Repayment Program and the National Health Service Corps Loan Repayment Program;

(e) The adequacy of the qualifications, the administrative and managerial ability and the experience of the

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State staff to administer and carry out the proposed project;

(f) The suitability of the applicant's approach and the degree to which the applicant's project is coordinated with Federal, State and other organized activities for meeting the State's health professions manpower needs and resources, including mechanisms for an ongoing evaluation of the program's activities;

(g) The source and plans for use of the State match (including the percentage of the State's match that is proposed to be used for loan repayments), the degree to which the State match exceeds 25% or has increased over time, and the amount of the match relative to the needs and resources of the States; and

(h) The extent to which special consideration will be extended to medically underserved areas with large minority populations.

§ 62.58 What other regulations apply?

Other regulations which apply to this subpart include but are not limited to:

- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of title VI of the Civil Rights Act of 1964
- 45 CFR part 81—Practice and procedure for hearings under part 80 of this title
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 86—Nondiscrimination on the basis of sex in programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
- 45 CFR part 50—Policies of general applicability: Subpart D—Public Health Service grant appeals procedure
- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 74—Administration of grants
- 45 CFR part 75—Informal grant appeals procedures
- 45 CFR part 92—Administrative Requirements for grants and cooperative agreements to State and local governments (effective October 1, 1988)

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Subpart D—Special Repayment Program

AUTHORITY: Sec. 215 of the Public Health Service Act 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 204, Pub. L. 100–177, 101 Stat. 1000.

SOURCE: 56 FR 56597, Nov. 6, 1991, unless otherwise noted.

§ 62.71 What is the scope and purpose of the Special Repayment Program?

These regulations apply to the Special Repayment Program authorized under section 204 of Pub. L. 100–177, which provides a time-limited opportunity for persons who were, on November 1, 1987, in breach of a written contract under the Public Health and National Health Service Corps Scholarship Training Program or the National Health Service Corps Scholarship Program to satisfy their scholarship obligations through full-time clinical service. These regulations do not apply to any Public Health and National Health Service Corps Scholarship Training Program or National Health Service Corps Scholarship Program obligation which the Secretary has determined was completely satisfied through service or monetary payment prior to November 1, 1987. The purpose of this program is to supply trained health professionals for the National Health Service Corps, which is used by the Secretary to improve the delivery of health services in health manpower shortage areas.

§ 62.72 Definitions.

In addition to the definitions in § 62.2 of this part, the following definitions will apply for purposes of this subpart:

Eligible defaulters means those individuals who, as of November 1, 1987, were:

- (1) In breach of a written contract entered into under section 338A of the Act and liable to the United States under section 338E(b) of the Act and/or in breach of a written contract entered into under section 225 of the Act (as in effect on September 30, 1977) and liable to the United States under section 225(f)(1) of the Act (as in effect on September 30, 1977); and

(2) Not already serving their obligations on December 1, 1987, under a judgment, forbearance agreement, or other written agreement to serve.

HPOL means the Health Manpower Shortage Area Placement Opportunity List described in section 204(b) of Pub. L. 100-177.

Match means that the Secretary has received documentation of:

(1) An offer of employment from a HPOL or SHPOL site which specifies at least the agreed upon salary and start date; and

(2) The Program participant's acceptance of that offer. Provided, however, that if the Program participant would be self-employed, a *match* means that the Secretary has approved a program participant's private practice option application under section 338D(a) of the Act.

Prior approved service means service performed prior to a Program participant's service start date under the Special Repayment Program:

(1) As a member of the National Health Service Corps pursuant to an assignment by the Secretary under section 333 of the Act;

(2) Under a written private practice option agreement signed by the Secretary pursuant to section 338D of the Act; or

(3) In compliance with section 338C(e) of the Act.

Program participant means an eligible defaulter whose contract under section 204 of Pub. L. 100-177 has been accepted and signed by the Secretary.

Scholarship amount means the sum of any amounts paid to, or on the behalf of, a scholarship recipient under the PH/NHSC Scholarship Training Program and/or the Scholarship Program.

SHPOL means the Supplemental Health Manpower Shortage Area Placement Opportunity List described in section 204(d) of Pub. L. 100-177.

Special Repayment Program or *Program* means the program authorized by section 204 of Pub. L. 100-177.

Total debt means the debt that would be owed by a Program participant under section 225(f)(1) of the Act, as in effect on September 30, 1977, and/or section 338E(b) of the Act, as if no payments had been made on the debt.

§ 62.73 What are the procedures for participation in the Special Repayment Program?

(a) *Notice of eligibility for participation in the program.* On or before February 29, 1988, the Secretary will, subject to paragraph (h) of this section, send written notice to each eligible defaulter of the opportunity provided under this Program. The notice will be sent to the last known address of each eligible defaulter and will describe the special repayment options available under the Program.

(b) *Selection of repayment method.* On or before May 29, 1988, eligible defaulters who wish to participate in this Program must sign and submit to the Secretary a written contract to provide service in accordance with either section 204(b) or section 204(c) of Pub. L. 100-177. The election between section 204(b) and section 204(c) of Pub. L. 100-177 is binding on the eligible defaulters.

(c) *Service sites.* Program participants will receive a listing of approved sites appropriate to the service option they have selected. Program participants electing service under section 204(b) of Pub. L. 100-177 will receive a HPOL. Program participants electing service under section 204(c) of Pub. L. 100-177 will receive a SHPOL. The HPOL or SHPOL sent to the Program participant will be specific to the Program participant's profession and his or her specialty training which is most needed by the National Health Service Corps. The Secretary is not required to identify placements for Program participants in a medical specialty for which the National Health service Corps has no need.

(d) *Time frames for matching and commencing service.* If a program participant electing to serve under section 204(b) of Pub. L. 100-177 chooses to serve at a remaining site on the 1988 HPOL, such participant must match to a site and must begin serving at the site by October 1, 1988. If a Program participant electing to serve under section 204(b) of Pub. L. 100-177 chooses to serve at a site on the 1989 HPOL, such participant must match to a HPOL site by February 15, 1989, and must begin service at the site by October 1, 1989. If a Program participant has elected to serve under section 204(c) of Pub. L.

100–177, such participant must match to a SHPOL site by May 15, 1989, and must begin service at that site by October 1, 1989.

(e) *Site visits.* The Program participant is responsible for the costs of any site visit(s) and any other contact with the site to obtain employment at the site.

(f) *Effect of failure to meet established time frames.* If a Program participant does not match to a site or begin service at that site within the time frames described in paragraph (d) of this section, the Secretary will determine that such individual is not relieved of his or her liability to the United States under the PH/NHSC Scholarship Training Program and/or Scholarship Program (including accrued interest and/or damages).

(g) *Service.* Service must be performed in accordance with subpart II of part D of title III of the Act. Service credit will begin after a Program participant has matched to a HPOL or SHPOL site and has commenced service at that site in accordance with subpart II of part D of title III of the Act.

(h) *Secretary's exclusion authority.* The Secretary is authorized, at any time, to deny or terminate an individual's participation in the Program for reasons related to the individual's professional competence or conduct.

§ 62.74 How much credit will a Program participant receive for monetary repayments made, or for approved service performed, before beginning service under the Special Repayment Program?

(a) Prior approved service performed by a Program participant will be credited to the Program participant for the purpose of calculating the Program participant's remaining service obligation under this Program. Thus, the Program participant's remaining service obligation will be calculated by subtracting the number of days of the Program participant's prior approved service from the number of days of the Program participant's original service obligation under the PH/NHSC Scholarship Training Program and/or the Scholarship Program. If a Program participant has made monetary payments, his or her remaining service obligation will be reduced by converting

the monetary payments into days of service credit as set forth in paragraph (b) or (c) of this section, whichever is applicable.

(b) Program participants who elect to serve pursuant to section 204(b) and section 204(c)(2) of Pub. L. 100–177, will not receive a refund of any amounts previously paid but will receive service credit for those payments as follows:

(1) The number of days of service credit will be calculated by dividing the total amount paid by the Program participant prior to the Program participant's service start date by the total debt as of the service start date and multiplying the result of that division by the number of days of the participant's remaining service obligation (as determined by the formula set forth in the second sentence of paragraph (a) of this section).

(2) If the Program participant defaults on a contract under this Program, prior monetary payments will not be credited to service but will be applied to the monetary debt owed by the Program participant.

(c) Program participants who elect to serve under section 204(c)(1) of Pub. L. 100–177 must pay an amount equal to the scholarship amount. Any amounts paid by the Program participant prior to or after entry into the Program, in accordance with § 62.76 of this subpart, will be used to reduce the Program participant's financial obligation incurred under section 204(c)(1) of Pub. L. 100–177. In some cases, the amounts paid before or after entry into the Program will exceed the scholarship amount. These payments in excess of the scholarship amount will be converted into days of service credit under the formula set forth in paragraph (b)(1) of this section. If a Program participant defaults on a contract under this option, the monies paid in excess of the scholarship amount will not be credited to service but will be credited toward the monetary debt owed by the Program participant under section 338E(b) of the Act or section 225(f)(1) of the Act, as in effect on September 30, 1977. The scholarship amount paid upon entering this option will be forfeited.

§ 62.75 Will individuals serving under the Special Repayment Program receive credit for partial service?

(a) With respect to obligations under the Scholarship Program, a credit will be allowed for partial service under the Special Repayment Program and will result in a reduction of the Program participant's financial obligation in accordance with the following formula:

$$A = 30 \frac{[t - (s + \frac{1}{2}r)]}{t}$$

In which:

'A' is the amount the United States is entitled to recover;

'0' is the sum of the amounts paid to or on behalf of the Program participant under the Scholarship Program and the interest on such amounts which would be payable if, at the time the amounts were paid, they were loans bearing interest at the maximum legal prevailing rate, as determined by the Treasurer of the United States;

't' is the sum of (1) the number of months of prior approved service plus (2) the number of months of the Program participant's period of obligated service under the Program including any additional months of service incurred pursuant to section 204(c)(2) of Pub. L. 100-177;

's' is the number of months of prior approved service performed by the Program participant before commencing service under this Program; and

'r' is the number of months of service performed by the Program participant in compliance with this Program.

However, where a judgment has been entered against a Program participant, the formula will be revised such that:

'30' is the amount of the judgment representing the Program participant's liability under the Scholarship Program, including any accrued post judgment interest and excluding any monetary payments on the judgment which may have been made by the Program participant;

't' is the sum of (1) the number of months of prior approved service performed by the Program participant after entry of the judgment but before commencing service under this Program plus (2) the number of months of the Program participant's period of obligated service under the Program including any additional months of service incurred pursuant to section 204(c)(2) of Pub. L. 100-177; and

's' is the number of months of prior approved service performed by the Program participant after the entry of the judgment but

before commencing service under this Program.

(b) With respect to obligations under the PH/NHSC Scholarship Training Program, if a Program participant fails to complete the period of obligated service under the Program (including any additional months of service incurred pursuant to section 204(c)(1) of Pub. L. 100-177), no credit for partial service under this Program will be allowed.

(c) Where participants have obligations under both the Scholarship Program and the PH/NHSC Scholarship Training Program, credit for service will be applied against the scholarship obligations in the order in which they were incurred.

§ 62.76 How will amounts of money due under the option under section 204(c)(1) of Public Law 100-177 be required to be repaid?

Program participants who elect to serve under section 204(c)(1) of Pub. L. 100-177 will be required to pay the full scholarship amount at least 60 days prior to the service start date specified in the documentation submitted to the Secretary.

PART 63—TRAINEESHIPS

Sec.

63.1 To what programs do these regulations apply?

63.2 Definitions.

63.3 What is the purpose of traineeships?

63.4 What are the minimum qualifications for awards?

63.5 How will NIH make awards?

63.6 How to apply.

63.7 What are the benefits of awards?

63.8 What are the terms and conditions of awards?

63.9 How may NIH terminate awards?

63.10 Other HHS regulations and policies that apply.

AUTHORITY: 42 U.S.C. 216, 282(b)(13), 284(b)(1)(C), 285a-2(b)(3), 286b-3, 287c-21(a).

SOURCE: 60 FR 10719, Feb. 27, 1995, unless otherwise noted.

§ 63.1 To what programs do these regulations apply?

(a) The regulations in this part apply to research traineeships awarded by the Director, NIH, each director of a national research institute of NIH, the

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Director of the National Library of Medicine, and the Director of the National Center for Complementary and Alternative Medicine, or their designees, pursuant to sections 402(b)(13), 405(b)(1)(C), 413(b)(3), 472, and 485(D)(a) of the Act, respectively.

(b) The regulations of this part do not apply to research training under the National Research Service Award Program governed by 42 CFR part 66 or to the Mental Health Traineeship Program governed by 42 CFR part 64a.

(c) Except as otherwise permitted under section 413(b)(3) of the Act, the regulations of this part do not apply to residency training of physicians or other health professionals.

[65 FR 66512, Nov. 6, 2000]

§ 63.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Award means an award of funds under sections 402(b)(13), 405(b)(1)(C), 413(b)(3), 472, 485D(a), or other sections of the Act which authorize research training or traineeships.

Awardee means an individual awarded a traineeship under sections 402(b)(13), 405(b)(1)(C), 413(b)(3), 472, 485D(a), or other sections of the Act which authorize research training or traineeships.

Director means the Director, NIH, the director of a national research institute of NIH, the Director of the National Library of Medicine, and the Director of the National Center for Complementary and Alternative Medicine, or any official of NIH to whom the authority involved has been delegated.

HHS means the Department of Health and Human Services.

Misconduct in science shall have the same meaning as prescribed in § 50.102 of this chapter.

NIH means the National Institutes of Health.

PHS means the Public Health Service.

Traineeship means an award under the regulations of this part to a qualified individual for that person's subsistence and other expenses during the period that person is participating in

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the research training approved under the award.

[60 FR 10719, Feb. 27, 1995, as amended at 65 FR 66513, Nov. 6, 2000]

§ 63.3 What is the purpose of traineeships?

The purpose of an NIH research traineeship is to provide support for financial subsistence to an individual during a period in which the awardee is acquiring training in:

(a) Basic and/or clinical biomedical or behavioral research relating to human health, including extending healthy life and reducing the burdens of illness, or

(b) Medical library science or related fields pertaining to sciences related to health or the communication of health sciences information.

Traineeships are intended to make available in the United States an increased number of persons having special competence in these research fields through developmental training and practical research experience in the facilities of NIH, with supplemental training at other qualified institutions (see § 63.8(a)).

§ 63.4 What are the minimum qualifications for awards?

Minimum qualifications for any traineeship shall be established by the Director and shall be uniformly applicable to all applicants in each traineeship program. These minimum qualifications may include requirements as to citizenship, medical standards, academic degrees, professional or other training or experience, and other factors as may be necessary to the fulfillment of the purpose of the traineeship. The Director may, as a matter of general policy or, in individual cases, waive compliance with any minimum qualification so established to the extent that the applicant or applicants have substantially equivalent qualifications or have such special training, experience or opportunity for service as to make an award particularly appropriate, and to the extent the Director finds it is consistent with the fulfillment of the purpose of the traineeship.

§ 63.5 How will NIH make awards?

Subject to the regulations of this part, the Director may award traineeships to those qualified applicants who are best able in that official's judgment to carry out the purpose of the traineeships. These awards may be made for a period of one (1) year or other period, including extensions or renewals, as may be specified.

§ 63.6 How to apply.

(a) Application for a traineeship shall be made in writing as prescribed by the Director.

(b) In addition to other pertinent information, the Director may require each applicant to submit the following information:

(1) Certification of the applicant's citizenship status;

(2) The applicant's educational background and other qualifications and experience, including previous academic and professional degrees, if any; and

(3) The subject area of the proposed training.

(c) By applying, eligible individuals agree to abide by HHS, PHS, and NIH regulations, and the terms and conditions of the traineeship award which may require compliance with policies and procedures that apply to the proper conduct of research, such as research involving human and animal subjects, patient care, hospital and laboratory procedures, handling of confidential information, and outside employment.

§ 63.7 What are the benefits of awards?

(a) Subject to the availability of funds, each individual awarded a traineeship may receive a stipend fixed in an amount determined by the Director.

(b) Additional allowances and benefits may be authorized by and at the discretion of the Director, taking into account the cost of living and other factors such as the requirements of the training program and availability of discretionary funds. Discretionary allowances and benefits may include: health benefits coverage; dependents' allowance; travel to pre-award interviews, to first duty station, and return to the place of origin upon conclusion of the traineeship; tuition and institu-

tion fees; and other specific costs as may be necessary to fulfill the purpose of the training program.

§ 63.8 What are the terms and conditions of awards?

All traineeships shall be subject to the following terms and conditions:

(a) Training must be carried out at a facility of the NIH, but may be supplemented by additional training acquired at another institution which is found by the Director to be directly related to the purpose of the traineeship and necessary to its successful completion.

(b) Payments shall be made to the awardee or to the institution for payment to the awardee in accordance with payment schedules as prescribed by the Director for each traineeship program.

(c) The awardee shall reimburse NIH for any overpayment of stipends or other allowances because of early termination of the traineeship or any other reason, unless waived for good cause shown by the awardee.

(d) The Director may establish procedures and requirements applicable to traineeship awards, consistent with the regulations in this part, regarding: (1) The proper conduct of research investigations, including research involving human and animal subjects; (2) patient care; (3) hospital and laboratory procedures; (4) handling of confidential information; (5) outside employment; and (6) additional conditions the Director finds necessary to fulfill the purpose of the traineeship.

(e) The awardee shall sign an agreement to comply with the terms and conditions of the traineeship.

§ 63.9 How may NIH terminate awards?

The Director may terminate a traineeship at any time:

(a) Upon written request of the awardee; or

(b) If it is determined that the awardee has committed misconduct in science, is ineligible, or has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which the award was made; or

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(c) If the awardee is convicted of a felony, or an offense involving any illegal drug or substance, or any offense involving a lack of financial integrity or business honesty; or

(d) Because of programmatic changes or lack of funds.

[65 FR 66513, Nov. 6, 2000]

§ 63.10 Other HHS regulations and policies that apply.

Several other policies and regulations apply to awards under this part. These include, but are not necessarily limited to:

45 CFR part 46—Protection of human subjects.

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants).

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effectuation of title VI of the Civil Rights Act of 1964.

45 CFR part 81—Practice and procedure for hearings under part 80 of this title.

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance.

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance.

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance.

59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. (NOTE: Interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, Bethesda, MD 20892-0161; telephone 301-402-1770 (not a toll-free number) to obtain copies of this policy.)

59 FR 34496 (July 5, 1994)—NIH Guidelines for Research Involving Recombinant DNA Molecules. (NOTE: Interested persons should contact the Office of Biotechnology Activities, NIH, Suite 323, 6000 Executive Boulevard, MSC 7010, Bethesda, MD 20892-7010; telephone 301-496-9838 (not a toll-free number) to obtain copies of the policy.)

“Public Health Service Policy on Humane Care and Use of Laboratory Animals” (Revised September 1986), Office of Laboratory Animal Welfare, NIH. (NOTE: Interested persons should contact the Office of Laboratory Animal Welfare, NIH, Rockledge Building I, 6705 Rockledge Drive, Suite 1050, MSC 7982, Bethesda, MD 20892-7982;

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telephone 301-496-7163 (not a toll-free number) to obtain copies of the policy.)

[60 FR 10719, Feb. 27, 1995, as amended at 65 FR 66513, Nov. 6, 2000]

PART 63a—NATIONAL INSTITUTES OF HEALTH TRAINING GRANTS

Sec.

63a.1 To what programs do these regulations apply?

63a.2 Definitions.

63a.3 What is the purpose of training grants?

63a.4 Who is eligible for a training grant?

63a.5 How to apply for a training grant.

63a.6 How are training grant applications evaluated?

63a.7 Awards.

63a.8 How long does grant support last?

63a.9 What are the terms and conditions of awards?

63a.10 How may training grant funds be spent?

63a.11 Other HHS regulations and policies that apply.

AUTHORITY: 42 U.S.C. 216, 242(b)(3), 284(b)(1)(C), 287c(b), 300cc-15(a)(1), 300cc-41(a)(3)(C), 7403(h)(2).

SOURCE: 61 FR 55111, Oct. 24, 1996, unless otherwise noted.

§ 63a.1 To what programs do these regulations apply?

(a) The regulations of this part apply to:

(1) Grants awarded by the John E. Fogarty International Center for Advanced Study in the Health Sciences, NIH, for training in international cooperative biomedical research endeavors, as authorized under section 307(b)(3) of the Act;

(2) Grants awarded by NIH for research training with respect to the human diseases, disorders, or other aspects of human health or biomedical research, for which the institute or other awarding component was established, for which fellowship support is not provided under section 487 of the Act and which is not residency training of physicians or other health professionals, as authorized by sections 405(b)(1)(C), 485B(b), 2315(a)(1), and 2354(a)(3)(C) of the Act; and,

(3) Grants awarded by the National Institute of Environmental Health Sciences, NIH, for the education and

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training of physicians in environmental health, as authorized under section 103(h)(2) of the Clean Air Act, as amended.

(b) The regulations of this part also apply to cooperative agreements awarded to support the training specified in paragraph (a) of this section. References to “grant(s)” shall include “cooperative agreement(s).”

(c) The regulations of this part do not apply to:

(1) Research training support under the National Research Service Awards Program (see part 66 of this chapter);

(2) Research training support under the NIH Center Grants programs (see part 52a of this chapter);

(3) Research training support under traineeship programs (see part 63 of this chapter);

(4) Research training support under the NIH AIDS Research Loan Repayment Program (see section 487A of the Act); or

(5) Research training support under the National Library of Medicine training grant programs (see part 64 of this chapter).

§ 63a.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

HHS means the Department of Health and Human Services.

NIH means the National Institutes of Health and its organizational components that award training grants.

Nonprofit as applied to any agency or institution, means an agency or institution which is a corporation or association, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

Program director means the single individual named by the grantee in the grant application and approved by the Secretary, who is responsible for the management and conduct of the training program.

Project period See § 63a.8(a).

Secretary means the Secretary of Health and Human Services and any other official of HHS to whom the authority involved is delegated.

Stipend means a payment to an individual to help meet that individual's

subsistence expenses during the training period.

Training grant means an award of funds to an eligible agency or institution for a training program authorized under § 63a.1 to carry out one or more of the purposes set forth in § 63a.3.

§ 63a.3 What is the purpose of training grants?

The purpose of a training grant is to provide financial assistance to an eligible agency or institution to enable it to provide research training to individuals in the diagnosis, prevention, treatment, or control of human diseases or disorders, or other aspects of human health or biomedical research, or in environmental health, in order to increase the number of facilities which provide qualified training and the number of persons having special competence in these fields.

§ 63a.4 Who is eligible for a training grant?

(a) *General.* Except as otherwise provided in this section or as prohibited by law, any public or private for-profit or nonprofit agency, institution, or entity is eligible for a training grant.

(b) *International training grants for AIDS research.* Any international organization concerned with public health is eligible for a training grant to support individuals for research training relating to acquired immunodeficiency syndrome (AIDS), as authorized under section 2315(a)(1) of the Act. In awarding these grants, preference shall be given to:

(1) Training activities conducted by, or in cooperation with, the World Health Organization and

(2) With respect to training activities in the Western Hemisphere, activities conducted by, or in cooperation with, the Pan American Health Organization or the World Health Organization.

§ 63a.5 How to apply for a training grant.

Any agency, institution, or entity interested in applying for a grant under this part must submit an application at the time and in the form and manner that the Secretary may require.

§ 63a.6 How are training grant applications evaluated?

The Secretary shall evaluate applications through the officers and employees, experts, consultants, or groups engaged by the Secretary for that purpose, including review or consultation with the appropriate advisory council or other body as may be required by law. The Secretary's evaluation will be for merit and shall take into account, among other pertinent factors, the significance of the program, the qualifications and competency of the program director and proposed staff, the adequacy of the selection criteria for trainees under the program, the adequacy of the applicant's resources available for the program, and the amount of grant funds necessary for completion of its objectives.

§ 63a.7 Awards.

Criteria. Within the limits of available funds, the Secretary may award training grants for training programs which:

- (a) Are determined to be meritorious, and
- (b) Best carry out the purposes of the particular statutory program described in § 63a.1 and the regulations of this part.

§ 63a.8 How long does grant support last?

(a) The notice of the grant award specifies how long the Secretary intends to support the project without requiring the grantee to recompete for funds. This period, called the "project period," will usually be for one to five years.

(b) Generally, the grant will be initially for one year and subsequent continuation awards will be for one year at a time. A grantee must submit a separate application at the time and in the form and manner that the Secretary may require to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of these awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require determination by the Secretary that con-

tinued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(d) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided that a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for that period, the Secretary may adjust the amounts awarded by withdrawing the excess.

§ 63a.9 What are the terms and conditions of awards?

In addition to the requirements imposed by law, grants awarded under this part are subject to any terms and conditions imposed by the Secretary to carry out the purpose of the grant or assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

§ 63a.10 How may training grant funds be spent?

(a) *Authorized expenditures; general.* A grantee shall expend funds it receives under this part solely in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the grant award, and the applicable cost principles in 45 CFR 74.27.

(b) *Authorized categories of expenditures.* Subject to any limitations imposed in the approved application and budget or as a condition of the award, grant funds may be expended for the following costs:

- (1) Expenses of the grantee in providing training and instruction under

the particular program, including salaries of faculty and support personnel, and the costs of equipment and supplies;

(2) Stipends and allowances to individuals during the period of their training and instruction; and,

(3) If separately justified and authorized under the particular program, tuition, fees, and trainee travel expenses which are necessary to carry out the purpose of the training grant.

(c) *Expenditures not authorized.* Grant funds may not be expended for:

(1) Compensation for employment or for the performance of personal services by individuals receiving training and instruction; or

(2) Payments to any individual who does not meet the minimum qualifications for training and instruction established by the grantee and approved by the Secretary or who has failed to demonstrate satisfactory participation in the training in accordance with the usual standards and procedures of the grantee.

§ 63a.11 Other HHS regulations and policies that apply.

Several other HHS regulations and policies apply to this part. These include, but are not necessarily limited to:

42 CFR part 50, subpart A—Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science

42 CFR part 50, subpart D—Public Health Service grant appeals procedure

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 46—Protection of human subjects

45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments

45 CFR part 75—Informal grant appeals procedures

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964

45 CFR part 81—Practice and procedure for hearings under part 80 of this title

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State and local governments

45 CFR part 93—New restrictions on lobbying
59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. [Note: this policy is subject to change, and interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, Bethesda, MD 20892-0161 (301-402-1770; not a toll-free number) to obtain references to the current version and any amendments.]

59 FR 34496 (July 5, 1994)—NIH Guidelines for Research Involving Recombinant DNA Molecules. [Note: this policy is subject to change, and interested persons should contact the Office of Recombinant DNA Activities, NIH, Suite 323, 6000 Executive Boulevard, MSC 7010, Bethesda, MD 20892-7010 (301-496-9838; not a toll-free number) to obtain references to the current version and any amendments.]

“PHS Grants Policy Statement,” DHHS Publication No. (OASH) 94-50,000 (Revised April 1, 1994), as amended by the Addendum, dated January 24, 1995. [Note: this policy is subject to change, and interested persons should contact the Extramural Outreach and Information Resources Office (EOIRO), Office of Extramural Research, 6701 Rockledge Drive, Room 6208, MSC 7910, Bethesda, MD 20892-7910 (301-435-0714; not a toll-free number) to obtain references to the current version and any amendments. Information may also be obtained by contacting the EOIRO via its e-mail address (ask_nih@odrockml.od.nih.gov) and by browsing the NIH Home Page site on the World Wide Web (<http://www.nih.gov>).]

“Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Office for Protection from Research Risks, NIH (Revised September 1986).

[NOTE: This policy is subject to change, and interested persons should contact the Office for Protection from Research Risks, NIH, Suite 3B01, 6100 Executive Boulevard, MSC 7507, Rockville, MD 20852-7507 (301-496-7005; not a toll-free number) to obtain references to the current version and any amendments.]

PART 64—NATIONAL LIBRARY OF MEDICINE TRAINING GRANTS

Sec.

- 64.1 Programs to which these regulations apply.
- 64.2 Definitions.
- 64.3 Who is eligible for a grant?
- 64.4 How to apply for a grant.
- 64.5 How are grant applications evaluated?
- 64.6 Awards.
- 64.7 What other conditions apply?
- 64.8 How may funds be used?
- 64.9 Other HHS regulations that apply.

AUTHORITY: 42 U.S.C. 216, 286b–3.

SOURCE: 56 FR 29192, June 26, 1991, unless otherwise noted.

§ 64.1 Programs to which these regulations apply.

(a) The regulations of this part apply to grants under section 472 of the Public Health Service Act (42 U.S.C. 286b–3) to public and private nonprofit institutions to assist in developing, expanding, and improving training programs (excluding training in a biomedical specialty and residency training) in library science and the field of communications of information pertaining to sciences relating to health.

(b) The regulations of this part also apply to cooperative agreements awarded for these purposes. References to “grant(s)” shall include “cooperative agreement(s).”

(c) The regulations of this part do not apply to research training support under the National Research Service Awards Program (see part 66 of this chapter).

§ 64.2 Definitions.

As used in this part:

HHS means the Department of Health and Human Services.

Nonprofit private entity means an agency, organization, institution, or other entity which may not lawfully hold or use any part of its net earnings to the benefit of any private shareholder or individual which does not hold or use its net earnings for that purpose.

Other trainee costs means those costs other than stipends, such as tuition, fees, and trainee travel, which are directly associated with and necessary for the training of individuals receiv-

ing stipends and which are incurred within the period of training.

Project director means the single individual named by the grantee in the grant application and approved by the Secretary, who is responsible for the management and conduct of the project.

Project period. See § 64.6(b).

Secretary means the Secretary of Health and Human Services and any other official of HHS to whom the authority involved is delegated.

Stipend means a payment to an individual that is intended to help meet that individual's subsistence expenses during training.

Training grant means an award of funds to an eligible entity for a project authorized under § 64.1(a).

§ 64.3 Who is eligible for a grant?

Except as otherwise prohibited by law, any public or private nonprofit entity is eligible for a training grant.

§ 64.4 How to apply for a grant.

Applications for grants must include the following information:

(a) *Required information on the proposed project.* (1) The nature, duration, and purpose of the training for which the application is filed.

(2) The name and qualifications of the project director and any key personnel responsible for the proposed project.

(3) A description of the facilities, staff, support services, and other organizational resources available to carry out the project.

(4) The intended number of trainees and the minimum qualifications and criteria for their selection.

(5) A description of the plan for evaluating the proposed project.

(6) Other pertinent information the Secretary may require to evaluate the proposed project.

(b) *Required information on costs.* (1) A budget for the proposed project and a justification of the amount of grant funds requested.

(2) If institutional expenses are requested, a separate statement of the amounts requested for personal services, equipment, supplies, or other non-personal services.

(3) If stipend costs are requested, a statement for each grant year of the estimated number of individuals to whom stipends will be provided and the length of time for which the stipend support will be provided. If other trainee costs are requested, they must be separately stated and justified.

(Approved by the Office of Management and Budget under control number 0925-0276)

§ 64.5 How are grant applications evaluated?

The Secretary shall evaluate applications through the officers and employees, experts, consultants, or groups engaged by the Secretary for that purpose. The Secretary's evaluation will be for technical merit and shall take into account, among other pertinent factors, the significance of the project, the qualifications and competency of the project director and proposed staff, the adequacy of selection criteria for trainees for the project, the adequacy of the applicant's resources available for the project, and the amount of grant funds necessary for completion of its objectives.

§ 64.6 Awards.

(a) *Criteria.* Within the limits of available funds, the Secretary may award training grants to carry out those projects which:

(1) Are determined by the Secretary to be technically meritorious; and

(2) In the judgment of the Secretary best promote the purpose of the grant program as authorized by section 472 of the Act (42 U.S.C. 286b-3), the regulations of this part (see § 64.1), and address program priorities.

(b) *Project period.* (1) The notice of grant award specifies how long the Secretary intends to support the project without requiring the project to recompute for funds. This period, called the project period, will usually be for one to five years.

(2) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of these awards will be made after consider-

ation of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(3) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(4) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for that period, the Secretary may adjust the amounts awarded by withdrawing the excess.

§ 64.7 What other conditions apply?

(a) Grants awarded under this part are subject to the following conditions:

(1) The grantee may not materially change the quality, nature, or duration of the project unless the written approval of the Secretary is obtained prior to the change.

(2) The grantee must submit to the Secretary, in the manner prescribed by the Secretary, the name and other pertinent information regarding each individual who is awarded a stipend under a grant.

(b) The Secretary may impose additional conditions prior to the award of any grant under this part if it is determined by the Secretary that the conditions are necessary to carry out the purpose of the grant.

(Approved by the Office of Management and Budget under control number 0925-0276)

§ 64.8 How may funds be used?

A grantee shall expend funds it receives under this part solely in accordance with the approved application and

§ 64.9

budget, the regulations of this part, the terms and conditions of the grant award, and the applicable cost principles in subpart Q of 45 CFR part 74. The funds may not be expended for:

(a) Compensation for employment or for the performance of personal services by individuals receiving training and instruction; or

(b) Payments to any individual who does not meet the minimum qualifications for training and instruction established by the grantee and approved by the Secretary or who has failed to demonstrate satisfactory participation in the training in accordance with the usual standards and procedures of the grantee.

§ 64.9 Other HHS regulations that apply.

Several other regulations apply to grants under this part. These include, but are not necessarily limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure.

45 CFR part 16—Procedures of the Departmental Grant Appeals Board.

45 CFR part 74—Administration of grants.

45 CFR part 75—Informal grant appeals procedures.

45 CFR part 76—subparts A-F.

Governmentwide debarment and suspension (nonprocurement) and requirements for drug-free workplace (grants).

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effectuation of title VI of the Civil Rights Act of 1964.

45 CFR part 81—Practice and procedure for hearings under 45 CFR part 80 of this title.

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance.

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance.

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance.

45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments.

42 CFR Ch. I (10–1–04 Edition)

PART 64a—OBLIGATED SERVICE FOR MENTAL HEALTH TRAINEESHIPS

Sec.

64a.101 Purpose.

64a.102 To whom do these regulations apply?

64a.103 Definitions.

64a.104 What requirements are imposed upon grantees?

64a.105 What are the conditions of obligated service?

AUTHORITY: Sec. 803, Pub. L. 96–398, 94 Stat. 1607–1608 (42 U.S.C. 242a).

SOURCE: 46 FR 39979, Aug. 5, 1981, unless otherwise noted.

§ 64a.101 Purpose.

This part establishes requirements to implement the service payback obligation of individuals who receive clinical traineeships in psychology, psychiatry, social work, or nursing (that are not of limited duration or experimental nature) under section 303 of the Public Health Service Act.

§ 64a.102 To whom do these regulations apply?

This part applies to any institution which receives a training grant under section 303 of the Public Health Service Act and to any individual who receives a stipend or other trainee allowances under such a grant for any period beginning on or after July 1, 1981, for clinical training in the field of psychology, psychiatry, nursing, or social work, except for training that is of a limited duration or experimental nature.

§ 64a.103 Definitions.

As used in this part:

Act means the Public Health Service Act as amended by Pub. L. 96–398.

Clinical traineeship means a stipend or other trainee allowances provided to an individual for clinical training in psychology, psychiatry, nursing, or social work, except for training that is of a limited duration or experimental nature, under a training grant authorized by section 303 of the Act.

Community Mental Health Centers Act means the Community Mental Health Centers Act (42 U.S.C. 2689 *et seq.*) other than Part D thereof.

Experimental nature refers to the training of undergraduates; the training of individuals in disciplines other than psychology, psychiatry, nursing, or social work; and any other training which the Secretary specifically designates as experimental in the notice of award for a training grant under section 303 of the Act.

Limited duration means a period that is equal to or less than 180 days, computed cumulatively over a two year period which begins on the first day of the clinical traineeship.

Mental Health Systems Act means the Mental Health Systems Act (42 U.S.C. 9401 *et seq.*).

Nonprofit private entity means an agency, organization, institution or other entity which may not lawfully hold or use any part of its net earnings to the benefit of any private shareholder or individual and which does not hold or use its net earnings for that purpose.

Other trainee allowances means financial assistance for those costs not covered by stipends, such as tuition, fees, and trainee travel, which are directly associated with and necessary to the training of individuals receiving stipends and are incurred within the period of training.

Secretary means the Secretary of Health and Human Services or other official of the Department to whom the authority involved has been delegated.

Stipend means financial assistance to an individual that is intended to help meet that individual's subsistence expenses during training.

§ 64a.104 What requirements are imposed upon grantees?

Recipients of training grants under section 303 of the Act that provide a clinical traineeship to any individual must:

(a) Give each such individual written notice of the service payback and recovery requirements of this part at the time the individual becomes a candidate for the traineeship;

(b) Before awarding a clinical traineeship, conduct an entrance interview with the individual in order to explain and emphasize the service obligation the individual is incurring, obtain the individual's written assurance that

he or she will satisfy the requirements of § 64a.105, and document, in accordance with paragraph (d) of this section, the entrance interview on the form containing the individual's written assurance.

(c) At the time of termination of the clinical traineeship,

(1) Notify the Secretary in writing of the date on which the individual's traineeship is terminated;

(2) Conduct an exit interview with the individual to remind the trainee of the service obligation, to fully explain the consequences that will incur should the trainee fail to satisfy the obligation, and, to tell the individual that the Secretary has been notified of the date of termination of the traineeship; and

(3) Document, in accordance with paragraph (d) of this section, the exit interview on the form notifying the Secretary of the termination of the traineeship.

(d) Document the entrance and exit interviews with at least the following information: The date of the interview, the names of the participants involved in the interview, and a statement that the interview included an explanation to the individual of the service payback requirement and the consequences of failing to fulfill the service payback requirement.

(Approved by the Office of Budget and Management under control number 0930-0120)

[46 FR 39979, Aug. 5, 1981, as amended at 52 FR 18359, May 15, 1987]

§ 64a.105 What are the conditions of obligated service?

In order to receive a clinical traineeship an individual must comply with the following conditions:

(a) *Written assurance.* Prior to the award of a clinical traineeship, the individual must sign a written assurance (in such form and manner as the Secretary prescribes) that he or she will satisfy the requirements of this section.

(b) *Commencement and crediting of service.* (1) An individual must start the obligated service within twenty-four months after termination of the clinical traineeship and carry out the service on a continuous basis unless, as

specified in paragraph (e) of this section, the individual has requested and had approved, respectively, an extension of the time for beginning the service, or a break in service.

(2) Following termination of the traineeship, the individual must annually provide (in such form and manner as the Secretary prescribes) a written report describing those previous years' activities which are related to service that fulfills the payback obligation. The Secretary will review this report and credit all service performed in those categories specified in paragraph (d) of this section toward the individual's payback obligation, except any service which is performed:

(i) Before termination of the individual's clinical traineeship; and

(ii) As part of any activity, such as course work, preparation of a dissertation or thesis, or practicum, which is needed to complete the training for which the individual received the traineeship.

(c) *Duration of obligation.* The period of service payback must equal the period of support under the clinical traineeship on a month for month basis.

(d) *Performance of the obligated service—(1) General requirements.* The obligated service must consist of the provision of service for which the individual was trained (in the training program for which the clinical traineeship was received) and must be performed on a full-time basis (not less than 30 hours per week averaged over the obligated service period).

(2) *Preferred service.* Except as provided under paragraph (d)(3) of this section, the individual must provide the obligated service in:

(i) A public inpatient mental institution;

(ii) Any entity which is receiving or has received a grant under the Mental Health Systems Act or the Community Mental Health Centers Act;

(iii) A psychiatric manpower shortage area designated by the Secretary under section 332 of the Public Health Service Act and 42 CFR part 5;

(iv) Any public or private nonprofit entity or in any nursing home (whether public, private nonprofit, or for profit) in which 50 percent or more of those

served are within one or more of the following groups: Racial or ethnic minorities (American Indian or Alaskan Native, Asian or Pacific Islander, Black, Hispanic), chronically mentally ill, mentally retarded, criminal or delinquent populations, rape victims, physically handicapped, abusers of alcohol, or persons addicted to drugs or other substances, children and adolescents, the elderly, poverty populations, migrants, members of the armed forces (or veterans if seen in a Federal facility), residents of areas other than those defined as urbanized by the Department of Commerce, or any other special populations, such as groups of refugees or disaster victims, which are specifically designated by the Secretary for this purpose.

(3) *Alternate service.* If the individual obtains the written approval of the Secretary, the individual may fulfill his or her obligation by:

(i) Serving in any public or private nonprofit entity or in any nursing home (whether public, private nonprofit, or for profit) in which not less than 25 percent of those served are within one or more of the underserved population groups listed in paragraph (d)(2)(iv) of this section. The individual must demonstrate a service commitment of more than 50 percent of his or her time to the targeted populations.

(ii) Teaching, conducting research, or conducting evaluation directed at improving alcohol, drug abuse or mental health services to one or more of the priority population groups listed in paragraph (d)(2)(iv) of this section, or working in a position which fosters the closer collaboration of health and alcohol, drug abuse or mental health services.

(iii) Providing in a public or private nonprofit entity consultation, training and education, liaison, community support or other professional services for which the individual was trained when the individual's work is directed toward improving alcohol, drug abuse or mental health services to the priority populations listed in paragraph (d)(2)(iv) of this section.

(e) *Conditions for deferral or break in service, waiver, or cancellation.* (1) Upon receipt of a written request showing good cause therefor by the individual

having a payback obligation, the Secretary may:

(i) Extend the period for beginning the obligated service (24 months after termination of the clinical traineeship), permit breaks in the required continuous service or extend the period for repayment under paragraph (g)(2) of this section, if it is determined that:

(A) An extension or break in service is necessary for the completion of training;

(B) Performance of the obligation must be delayed because a temporary disability makes present performance impossible; or

(C) Performance of the obligation must be delayed because present performance would involve a substantial hardship and failure to extend the period would be against equity and good conscience.

(ii) Waive, in whole or in part, the service payback and recovery requirements of this section if it is determined that fulfillment would be impossible because the individual is permanently and totally disabled.

(iii) In making determinations under § 64a.105(e)(1)(i)(C), the Secretary will take into consideration the following factors:

(A) The individual's present financial resources and obligations;

(B) The individual's estimated future financial resources and obligations;

(C) The reasons for the individual's failure to complete the requirements within the prescribed period, such as problems of a personal nature;

(D) The unavailability of employment opportunities appropriate to the individual's education and training; and

(E) Any other extenuating circumstances.

(2) Upon receipt of written notice giving evidence of a conflicting obligation under section 752 or 753 of the Act or of an election to fulfill an obligation under section 472 of the Act prior to an obligation under this section, the Secretary will extend the period for beginning service (24 months after termination of the clinical traineeship), permit breaks in the required continuous service or extend the period for repay-

ment under paragraph (g)(1), as appropriate.

(3) The service payback and recovery obligations of an individual will be cancelled upon the submission to the Secretary of a certificate of that individual's death or other evidence which the Secretary determines to be satisfactory.

(f) *Conflicting or multiple payback obligations.* In any case where the individual has, in addition to a payback obligation incurred under this section, an obligation to perform service under section 752 or 753 of the Act (because of receipt of a National Health Service Corps scholarship) or under section 472 of the Act (because of receipt of a National Research Service Award), or both, performance of the same activity may not be counted toward more than one of these obligations. In determining the order in which obligations must be fulfilled, obligations under section 752 or 753 take precedence over obligations incurred under this section. However, with respect to obligations under this section and 472, the individual may elect which obligation to fulfill first. Any individual who has an obligation under section 752 or 753 or makes an election to fulfill an obligation under section 472 prior to an obligation under this section, must give written notice to the Secretary as provided by paragraph (e)(3) of this section.

(g) *Recovery for failure to perform obligated service.* (1) If an individual fails to begin or complete the obligated service in accordance with the requirements of paragraphs (a) through (f) of this section, that individual is obligated to repay the United States an amount equal to three times the cost of the award (including stipends and other trainee allowances) plus interest on that amount calculated for the total period since the trainee failed to perform the obligated service at the rate set by the Secretary of the Treasury for National Research Service Awards prevailing on the date on which the period of appointment begins, multiplied, in any case in which the service that was required has been performed in part, by the percentage which the length of service that was not performed is to the length of the service

that was required to be performed. The amount will be determined under the following formula:

$$A = 3(\theta + mi\theta) \frac{(t-s)}{(t)}$$

where

A = the amount the United States is entitled to recover;

θ = the cost of the clinical traineeship (including stipends and other trainee allowances);

m = the number of months since the trainee failed to perform obligated service;

i = the National Research Service Award rate on the date which the period of appointment begins divided by twelve;

t = the total number of months of the service obligation;

s = the number of months that have been served.

(2) Unless the Secretary extends the repayment period as provided in paragraph (e) of this section, the individual shall pay to the United States the total amount which the United States is entitled to recover under paragraph (g)(1) of this section immediately upon the date that the individual fails to begin or complete the period of obligated service (including failing to comply with the applicable terms and conditions of an extension or break in service granted the individual) or upon the date that the individual indicates his or her intention not to fulfill the service obligation as determined by the Secretary. The amount is considered a debt owed to the United States, with interest accruing monthly upon the total debt as provided under paragraph (g)(1) of this section.

[46 FR 39979, Aug. 5, 1981, as amended at 52 FR 18359, May 15, 1987]

PART 65—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES HAZARDOUS WASTE WORKER TRAINING

Sec.

65.1 To what projects do these regulations apply?

65.2 Definitions.

65.3 Who is eligible to apply for a grant?

65.4 Project requirements.

65.5 How will applications be evaluated?

65.6 How long does grant support last?

65.7 For what purposes may grant funds be spent?

65.8 What additional Department regulations apply to grantees?

65.9 Additional conditions.

AUTHORITY: 42 U.S.C. 9660a; 49 U.S.C. App. 1816.

SOURCE: 55 FR 42568, Oct. 22, 1990, unless otherwise noted.

§ 65.1 To what projects do these regulations apply?

(a) The regulations in this part apply to:

(1) The program of grants for the training and education of workers who are or are likely to be engaged in activities related to hazardous waste removal or containment, or emergency response that is authorized under section 126(g) of the SARA; and

(2) The program of grants to support qualified non-profit organizations for the purpose of providing training and education to hazardous materials employees regarding: the safe unloading, loading, handling, storage, and transportation of hazardous materials; and, emergency preparedness for responding to accidents or incidents involving the transportation of hazardous materials that is authorized under section 118 of the HMTA.

(b) Grants are available for curriculum and training materials development, technical support of training, direct student training, training program evaluation and related activities. Target populations for this training are workers and supervisors who are or are likely to be engaged in hazardous substance removal or other activities which expose or potentially expose these workers to hazardous substances in activities such as:

(1) Waste handling and processing at waste generators and active and inactive hazardous substance treatment, storage, and disposal facilities;

(2) Clean up, removal, containment, or remedial actions at waste sites;

(3) Hazardous substance emergency response;

(4) Hazardous substance disposal site risk assessment and investigation, clean up, or remedial actions; and

(5) Transportation of hazardous wastes.

Target populations may also be regulated under standards promulgated by the Secretary of Labor, the Secretary

of Transportation, the Administrator of the Environmental Protection Agency, and other agencies under section 126(g) of the SARA or section 106(b) of the HMTA.

(c) Two types of grants are available: Program grants covering the full range of activities, including program development, direct worker training and education, and program evaluation; and planning grants under the SARA.

(1) Planning grants are intended to assist organizations which demonstrate potential for providing hazardous worker training, but need additional developmental efforts prior to initiation of full curriculum development and training activities. A limited number of one-year planning grants may be funded at a level determined appropriate by the Director. After successful completion of a one-year planning grant, a recipient may apply for a full program grant on a competitive basis.

(2) Full program grants will be awarded to organizations with demonstrated capability to provide worker health and safety training and education and demonstrated ability to identify, describe, and access target populations. Full program grantees must be able to immediately initiate curriculum development and worker training activities.

[55 FR 42568, Oct. 22, 1990; 59 FR 64141, Dec. 13, 1994]

§ 65.2 Definitions.

As used in this part:

Award or *grant* means a grant or cooperative agreement made under section 126(g) of the SARA or section 118 of the HMTA.

Director means the Director, National Institute of Environmental Health Sciences, or the Director's delegate.

HHS means the Department of Health and Human Services.

HMTA means the Hazardous Materials Transportation Act, as amended (49 U.S.C. App. 1801 *et seq.*).

NIEHS means the National Institute of Environmental Health Sciences, an organizational component of the National Institutes of Health, as authorized by sections 401(b)(1)(L) and 463 of the Public Health Service Act (42 U.S.C. 281(b)(1)(L) and 285(l)).

NIH means the National Institutes of Health.

Nonprofit as applied to any agency, organization, institution, or other entity means a corporation or association no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

SARA means the Superfund Amendments and Reauthorization Act of 1986, Public Law 99-499, as amended (42 U.S.C. 9601 *et seq.*).

Stipend means a payment to an organization that is intended to help meet that organization's subsistence expenses for trainees during the training period.

Training grant means an award of funds to an eligible entity for a project authorized under § 65.1.

[55 FR 42568, Oct. 22, 1990; 59 FR 64141, Dec. 13, 1994]

§ 65.3 Who is eligible to apply for a grant?

Public and private nonprofit entities providing worker health and safety education and training may apply for grants under these regulations. Applicants for a grant may use services, as appropriate, of other public or private organizations necessary to develop, administer, or evaluate proposed worker training programs so long as the majority of the work is done by the applicant.

§ 65.4 Project requirements.

In addition to meeting the requirements specified in the application, the instructions accompanying it, and the regulations referred to in § 65.8, each applicant must meet the following requirements:

(a) Two or more nonprofit organizations may join in a single application and share grant resources in order to maximize worker group coverage, enhance the effectiveness of training, and bring together appropriate academic disciplines and talents. Joint applications must describe the cooperative arrangements for program integration and effectiveness. Specific expertise, facilities, or services to be provided by each participating member must be identified.

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(b) Each applicant must detail the nature, duration, and purpose of the training for which the application is filed. The proposed training program must meet the standards promulgated by the Secretary of Labor and Secretary of Transportation under section 126(g) of the SARA or section 106(b) of the HMTA, and such additional requirements as the Director may prescribe to ensure appropriate health and safety training.

(c) The applicant must provide assurance that the applicant will not discriminate in the selection of trainees or instructors on the basis of membership or nonmembership in a union.

[55 FR 42568, Oct. 22, 1990; 59 FR 64141, Dec. 13, 1994]

§ 65.5 How will applications be evaluated?

(a) The Director shall evaluate applications through the officers and employees, and experts and consultants engaged by the Director for that purpose. The Director's first level of evaluation will be for technical merit and shall take into account, among other pertinent factors, the significance of the project, the qualifications and competency of the project director and proposed staff (including the ability to manage complex training programs), the adequacy of selection criteria for trainees for the project, the adequacy of the detailed training plan including provision for hands-on training, the adequacy of the applicant's resources available for the project, the amount of grant funds necessary for completion of its objectives, and how well the projects meet training criteria in OSHA's Hazardous Waste Operations and Emergency Response Regulation (29 CFR 1910.120) and/or how well they cover the target populations listed in § 65.1(b). A second level of review will be conducted for program relevance.

(b) Within the limits of funds available, the Director may award training grants to carry out those projects which have satisfied the requirements of the regulations of this part; are determined by the Director to be technically meritorious; and in the judgment of the Director best promote the purposes of the grant programs authorized by section 126(g) of the SARA or

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section 118 of the HMTA, the regulations of this part, and program priorities.

[55 FR 42568, Oct. 22, 1990; 59 FR 64141, Dec. 13, 1994]

§ 65.6 How long does grant support last?

(a) The notice of grant award specifies how long NIEHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 1–5 years.

(b) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices and the availability of funds. In all cases, continuation awards require a determination by the NIEHS that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 65.7 For what purposes may grant funds be spent?

Individuals receiving training shall be entitled only to the stipends and allowances included in a budget approved by the Director, taking into account the cost of living and such other factors as the needs of the program and the availability of funds.

§ 65.8 What additional Department regulations apply to grantees?

Several other regulations and policies apply to grants under this part. These include, but are not limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure.

45 CFR part 16—Procedures of the Departmental Grant Appeals Board.

45 CFR part 74—Administration of grants.

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- 45 CFR part 75—Informal grant appeals procedures.
- 45 CFR part 76, subparts A–F—Government-wide debarment and suspension (non-procurement) and government-wide requirements for drug-free workplace (grants).
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of title VI of the Civil Rights Act of 1964.
- 45 CFR part 81—Practice and procedure for hearings under part 80 of this title.
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance.
- 45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance.
- 45 CFR part 91—Nondiscrimination on the basis of age in Health and Human Services programs and activities receiving Federal financial assistance.
- 45 CFR part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and local Governments.
- 45 CFR part 93—New restrictions on lobbying.

§ 65.9 Additional conditions.

The Director may with respect to any award impose additional conditions prior to, or at the time of, any award when, in the Director's judgment, such conditions are necessary to assure the carrying out of the purposes of the award, the interest of the public health, or the conservation of funds awarded.

PART 65a—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES HAZARDOUS SUBSTANCES BASIC RESEARCH AND TRAINING GRANTS

Sec.

- 65a.1 To what programs do these regulations apply?
- 65a.2 Definitions.
- 65a.3 Who is eligible to apply for a grant?
- 65a.4 What are the program requirements?
- 65a.5 How to apply.
- 65a.6 How will applications be evaluated?
- 65a.7 Awards.
- 65a.8 How long does grant support last?
- 65a.9 What are the terms and conditions of award?
- 65a.10 For what purposes may grant funds be spent?

65a.11 Other HHS regulations and policies that apply.

AUTHORITY: 42 U.S.C. 216, 9660(a).

SOURCE: 61 FR 55114, Oct. 24, 1996, unless otherwise noted.

§ 65a.1 To what programs do these regulations apply?

(a) The regulations of this part apply to the award of grants to support programs for basic research and training directed towards understanding, assessing, and attenuating the adverse effects on human health resulting from exposure to hazardous substances, as authorized under section 311(a) of the Act (42 U.S.C. 9660(a)). The purpose of these programs is to carry out coordinated, multi-component, interdisciplinary research consisting of at least three or more biomedical research projects relating to hazardous substances and at least one non-biomedical research project in the fields of ecology, hydrogeology, and/or engineering, and including the training of investigators as part of the grantee's overall program.

(b) The regulations of this part also apply to cooperative agreements awarded to support the programs described in paragraph (a) of this section. References to "grant(s)" shall include "cooperative agreement(s)."

(c) The regulations of this part do not apply to:

(1) Research training support under the National Research Service Awards Program (see part 66 of this chapter),

(2) Research, demonstration, and training support under the NIH Center Grants programs (see part 52a of this chapter),

(3) Research training support under traineeship programs (see parts 63 and 64a of this chapter), or

(4) Research training support under the NIH AIDS Research Loan Repayment Program authorized under section 487A of the Public Health Service Act, as amended (42 U.S.C. 288–1).

§ 65a.2 Definitions.

As used in this part:

Act means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (42 U.S.C. 9601 *et seq.*).

Award or grant means a grant or co-operative agreement awarded under section 311(a) of the Act (42 U.S.C. 9660(a)).

Director means the Director of the National Institute of Environmental Health Sciences, or the Director's delegate.

HHS means the Department of Health and Human Services.

Institution of higher education means an educational institution in any state which (1) admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, (2) is legally authorized within the state to provide a program of education beyond secondary education, (3) provides an educational program for which it awards a bachelor's degree or provides not less than a two-year program which is acceptable for full credit toward a bachelor's degree, (4) is a public or other nonprofit institution, and (5) is accredited by a nationally recognized accrediting agency or association or, if not so accredited, (i) is an institution with respect to which the Secretary of Education has determined that there is satisfactory assurance, considering the resources available to the institution, the period of time, if any, during which it has operated, the effort it is making to meet accreditation standards, and the purpose for which this determination is being made, that the institution will meet the accreditation standards of a nationally recognized accrediting agency or association within a reasonable time, or (ii) is an institution whose credits are accepted, on transfer, by not less than three institutions which are so accredited, for credit on the same basis as if transferred from an institution so accredited. The term also includes any school which provides not less than a one-year program of training to prepare students for gainful employment in a recognized occupation and which meets the provisions of paragraphs (1), (2), (4), and (5) of this definition. The term also includes a public or nonprofit private educational institution in any state which, in lieu of the requirement in paragraph (1), admits as regular students persons who

are beyond the age of compulsory school attendance in the state in which the institution is located and who meet the requirements of section 1091(d) of title 20 U.S. Code, as amended. For purposes of this definition, the Secretary of Education publishes a list of nationally recognized accrediting agencies or associations which that official determines to be reliable authority as to the quality of training offered. This list is found in the brochure, "Nationally Recognized Accrediting Agencies and Associations Criteria and Procedures for Listing by the U.S. Secretary of Education and Current List."

[NOTE: This brochure is subject to change, and interested persons should contact the U.S. Department of Education Office of Post-Secondary Education, Accreditation and State Liaison Division, ROB 3, 7th and D Streets, S.W., Room 37-15, Washington, DC 20202-5244 (202-708-7417; not a toll-free number) to obtain a current version of the brochure and any amendments.]

NIEHS means the National Institute of Environmental Health Sciences, an organizational component of the National Institutes of Health, as authorized under sections 401(b) and 463 of the Public Health Service Act, as amended (42 U.S.C. 281(b) and 185f).

NIH means the National Institutes of Health.

Nonprofit, as applied to any agency, organization, institution, or other entity, means a corporation or association no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

PHS means the Public Health Service.

Program means the activity to carry out research and training supported by a grant under this part.

Program director means the single individual designated by the grantee in the grant application and approved by the Director, who is responsible for the scientific and technical direction of the research component and the conduct of the training component under a program.

Project period means the period of time, from one to five years, specified in the notice of grant award that NIEHS intends to support a proposed

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program without requiring the program awardee to recompete for funds.

Secretary means, unless the context otherwise requires, the Secretary of Health and Human Services or other official of HHS to whom the authority involved is delegated.

§ 65a.3 Who is eligible to apply for a grant?

(a) Except as otherwise prohibited by law, any public or private nonprofit institution of higher education may apply for an award under this part.

(b) Awardee institutions may carry out portions of the research or training components of an award through contracts with appropriate organizations, including:

- (1) Generators of hazardous wastes;
- (2) Persons involved in the detection, assessment, evaluation, and treatment of hazardous substances;
- (3) Owners and operators of facilities at which hazardous substances are located; and
- (4) State and local governments.

§ 65a.4 What are the program requirements?

The applicant shall include the following in its proposed program for which support is requested under this part:

(a) *Basic research component.* The program shall include three or more meritorious biomedical research projects, including epidemiologic studies relating to the study of the adverse effects of hazardous substances on human health, and at least one meritorious project involving hydrogeologic or ecologic research which shall cumulatively address:

- (1) Methods and technologies to detect hazardous substances in the environment;
- (2) Advanced techniques for the detection, assessment, and evaluation of the effects of these substances on human health;
- (3) Methods to assess the risks to human health presented by these substances; and
- (4) Basic biological, chemical, and/or physical methods to reduce the amount and toxicity of these substances.

(b) *Training component.* The program shall include the following kinds of

training, as part of or in conjunction with the basic research component:

(1) Graduate training in environmental and occupational health and safety and in public health and engineering aspects of hazardous waste control; and/or

(2) Graduate training in the geosciences, including hydrogeology, geological engineering, geophysics, geochemistry, and related fields, necessary to meet professional personnel needs in the public and private sectors and to carry out the purposes of the Act; and

(3) Worker training relating to handling hazardous substances, which includes short courses and continuing education for state and local health and environmental agency personnel and other personnel engaged in the handling of hazardous substances, in the management of facilities at which hazardous substances are located, and in the evaluation of the hazards to human health presented by these facilities.

§ 65a.5 How to apply.

Each institution desiring a grant under this part must submit an application at the time and in the form and manner as the Secretary may require.

§ 65a.6 How will applications be evaluated?

The Director shall evaluate applications through the officers and employees, experts, consultants, or groups engaged by the Director for that purpose, including review by the National Advisory Environmental Health Sciences Council in accordance with peer review requirements set forth in part 52h of this chapter. The Director's first level of evaluation will be for technical merit and shall take into account, among other pertinent factors, the significance of the program, the qualifications and competency of the program director and proposed staff, the adequacy of the applicant's resources available for the program, and the amount of grant funds necessary for completion of its objectives. A second level of review will be conducted by the National Advisory Environmental Health Sciences Council.

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§ 65a.7 Awards.

Criteria. Within the limits of available funds, the Director may award grants to carry out those programs which:

(a) Are determined by the Director to be meritorious; and

(b) In the judgment of the Director, best promote the purposes of the grant program, as authorized under section 311(a) of the Act and the regulations of this part, and best address program priorities.

§ 65a.8 How long does grant support last?

(a) The notice of grant award specifies how long NIEHS intends to support the project without requiring the grantee to recompet for funds. This period, called the project period, may be for 1–5 years.

(b) Generally, the grant will initially be for one year, and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application at the time and in the form and manner as the Secretary may require to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of these awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Director that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application.

(d) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Director, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Director that the amount of Federal funds awarded and available to the grantee for that period, including any

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unobligated balance carried forward from prior periods, exceeds the grantee's needs for that period, the Director may adjust the amounts awarded by withdrawing the excess.

§ 65a.9 What are the terms and conditions of awards?

In addition to being subject to other applicable regulations (see § 65a.11), grants awarded under this part are subject to the following terms and conditions:

(a) *Material changes.* Except as otherwise provided by 45 CFR 74.25, the grantee may not materially change the quality, nature, scope, or duration of the program unless the written approval of the Director is obtained prior to the change.

(b) *Additional conditions.* The Director may impose additional conditions prior to the award of any grant under this part if it is determined by the Director that the conditions are necessary to carry out the purpose of the grant or assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

§ 65a.10 For what purposes may grant funds be spent?

A grantee shall spend funds it receives under this part solely in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR 74.27.

§ 65a.11 Other HHS regulations and policies that apply.

Several other HHS regulations and policies apply to awards under this part. These include but are not necessarily limited to:

- 42 CFR part 50, subpart A—Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science
- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure
- 42 CFR part 50, subpart F—Responsibility of applicants for promoting objectivity in research for which PHS funding is sought
- 42 CFR part 52h—Scientific peer review of research grant applications and research and development contract projects

- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 46—Protection of human subjects
- 45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments
- 45 CFR part 75—Informal grant appeals procedures
- 45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964
- 45 CFR part 81—Practice and procedure for hearings under part 80 of this title
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance
- 45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
- 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments
- 45 CFR part 93—New restrictions on lobbying
- 59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

[NOTE: This policy is subject to change, and interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, Bethesda, MD 20892-0161 (301-402-1770; not a toll-free number) to obtain references to the current version and any amendments.]

- 59 FR 34496 (July 5, 1994)—NIH Guidelines for Research Involving Recombinant DNA Molecules.

NOTE: This policy is subject to change, and interested persons should contact the Office of Recombinant DNA Activities, NIH, Suite 323, 6000 Executive Boulevard, MSC 7010, Bethesda, MD 20892-7010 (301-496-9838; not a toll-free number) to obtain references to the current version and any amendments.]

"PHS Grants Policy Statement," DHHS Publication No. (OASH) 94-50,000 (Revised April 1, 1994), as amended by Addendum, dated January 24, 1995.

NOTE: This policy is subject to change, and interested persons should contact the Extramural Outreach and Information Resources

Office (EOIRO), Office of Extramural Research, 6701 Rockledge Drive, Room 6208, MSC 7910, Bethesda, MD 20892-7910 (301-435-0714; not a toll-free number) to obtain references to the current version and any amendments. Information may also be obtained by contacting the EOIRO via its e-mail address (asknih@odrockml.od.nih.gov) and by browsing the NIH Home Page site on the World Wide Web (<http://www.nih.gov>).]

"Public Health service Policy on Humane Care and Use of Laboratory animals," Office for Protection from Research Risks, HHS (Revised September 1986).

NOTE: This policy is subject to change, and interested persons should contact the Office for Protection from Research Risks, NIH, Suite 3B01, 6100 Executive Boulevard, MSC 7507, Rockville, MD 20852-7507 (301-496-7005; not a toll-free number) to obtain references to the current version and any amendments.]

PART 66—NATIONAL RESEARCH SERVICE AWARDS

Subpart A—Direct Awards

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- 66.201 Applicability.
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AUTHORITY: 42 U.S.C. 216, 288.

SOURCE: 48 FR 24880, June 3, 1983, unless otherwise noted.

Subpart A—Direct Awards

§ 66.101 Applicability.

The regulations in this subpart apply to National Research Service Awards made by the Secretary to individuals for research and training to undertake research, under section 487 of the Public Health Service Act, as amended (42 U.S.C. 288).

[66 FR 29499, May 31, 2001]

§ 66.102 Definitions.

As used in this subpart:

(a) *Act* means the Public Health Service Act, as amended.

(b) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) *Nonprofit institution* means a corporation or association in which no part of the net earnings inures or may lawfully inure to the benefit of any private shareholder or individual.

(d) *Award* means a National Research Service Award under section 487 of the Act (42 U.S.C. 288).

(e) *Residency* means post-graduate training for doctors of medicine, osteopathy, dentistry, optometry, and podiatry, nurses, and other individuals providing health care directly to patients, in which the majority of the time is spent in non-research clinical training.

(f) *Noncitizen national of the United States* means a person who, though not a citizen of the United States, owes permanent allegiance to the United States [8 U.S.C. 1101(a) (22)].

(g) *Predoctoral training* means training at the post-baccalaureate level in a program leading to the award of a doctor of philosophy of science, or equivalent degree. For purposes of Awards under the Minority Access to Research Careers programs of the National Institute of General Medical Sciences and the Career Opportunities in Research Education and Training programs of the National Institute of Mental Health, *predoctoral training* also means training in a program leading to the award of a baccalaureate in science or equivalent degree.

(h) *Postdoctoral training* means training of individuals holding a doctor of philosophy, science, medicine, dentistry, osteopathy, optometry, podiatry, veterinary medicine, engineering, nursing sciences, public health, or equivalent degree.

[48 FR 24880, June 3, 1983, as amended at 66 FR 29499, May 31, 2001]

§ 66.103 Eligibility.

To be eligible for a National Research Service Award an individual must:

(a) Be a citizen, noncitizen national of the United States, or lawfully admitted to the United States for permanent residence at the time of the award.

(b) Propose to engage in such research, or training to undertake research, in a program specified in section 487(a)(1)(A) of the Act; and

(c) Propose to engage in such research or training to undertake research on a full-time basis except in cases of disability or pressing family need.

[48 FR 24880, June 3, 1983, as amended at 66 FR 29500, May 31, 2001]

§ 66.104 Application.

(a) Eligible individuals may apply for an Award using the form and by the dates the Secretary prescribes.

(b) In addition to any other pertinent information that the Secretary may require, each application shall detail:

(1) The applicant's educational background and other qualifications and experience, including previous academic and professional degrees;

(2) The subject area of the proposed research or training;

(3) The proposed period of Award;

(4) If the proposed period of Award would provide the individual with aggregate support in excess of five years at the predoctoral level or three years at the postdoctoral level, the justification for this request; and

(5) The availability of necessary resources and facilities at the institution

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where the research or training would be conducted.

(Approved by the Office of Management and Budget under control number 0925-0002)

[48 FR 24880, June 3, 1983, as amended at 66 FR 29500, May 31, 2001]

§ 66.105 Requirements.

The Secretary shall make an Award to an individual under this subpart only if:

(a) For any Award made for an individual's initial twelve months of NRSA postdoctoral research or training, the individual has assured the Secretary, in the form and manner the Secretary may prescribe, that he or she will satisfy the requirements of § 66.110.

(b) If the proposed research or training would take place at an institution other than the National Institutes of Health, the institution has assured the Secretary, in the form and manner the Secretary may prescribe, that:

(1) The applicant has been accepted to the institution for the purpose of engaging in the research or training for which an Award is being sought;

(2) The Award will not be used to support a residency; and

(3) In the event an Award is made the institution will make available to the applicant any resources and facilities described in the application as necessary to carry out the research or training; and

(c) The individual has assured the Secretary, in the form and manner the Secretary may prescribe, that the Award to the individual will not be used to support a residency.

(Approved by the Office of Management and Budget under control number 0925-0002)

[48 FR 24880, June 3, 1983, as amended at 66 FR 29500, May 31, 2001]

§ 66.106 Awards.

(a) Within the limits of funds available, the Secretary shall make Awards to those applicants:

(1) Who have satisfied the requirements of § 66.105; and

(2) Whose proposed research or training would, in the judgment of the Secretary, best promote the purposes of section 487(a)(1)(A) of the Act, taking into consideration among other pertinent factors:

(i) The scientific, technical, or educational merit of the particular proposal;

(ii) The availability of resources and facilities to carry it out;

(iii) The qualifications and experience of the applicant; and

(iv) The need for personnel in the subject area of the proposed research or training.

(b) In making Awards, the Secretary shall take account of the Nation's overall need for biomedical research by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(c) All Awards shall be in writing. Each shall specify:

(1) The period of the Award;

(2) The total recommended stipends and allowances provided for the entire Award period;

(3) The amount awarded for the initial year of that period (see § 66.107); and

(4) The amount of the payments to the institution for the cost of services provided the awardee by the institution during the initial year of that period (see § 66.108).

(d) Neither the approval of any application nor any Award shall commit or obligate the United States in any way to make additional, supplemental, continuation, or other Award with respect to any approved application or portion thereof.

(e) No individual may receive an aggregate of more than five years of support at the predoctoral level and three years at the postdoctoral level unless the Secretary waives, for good cause shown, this limitation for the individual. In determining what constitutes "good cause," the Secretary shall take into account such factors as whether the applicant proposes to pursue a combined program leading to the degrees of doctor of medicine and doctor of philosophy.

[48 FR 24880, June 3, 1983, as amended at 66 FR 29500, May 31, 2001]

§ 66.107 Payments to awardees.

(a) Individuals receiving Awards shall be entitled to the stipends, tuition, fees, and allowances the Secretary may designate, taking into account the cost

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of living, and such other factors as the needs of the program and the availability of funds.

(b) The Secretary shall pay stipends, tuition, fees and allowances to the awardee or the sponsoring institution for payment to the awardee.

§ 66.108 Payments to institutions.

The institution shall be entitled to an allowance to help defray the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided to the individual by the institution. The Secretary shall determine the amount of payments based upon reasonable costs to the institution of establishing and maintaining the quality of research and training programs for which it receives support under this subpart. The Secretary may make payments to the institution either in advance or by way of reimbursement.

§ 66.109 Termination.

(a) The Secretary may terminate an Award prior to its normal expiration date:

(1) At the written request of the awardee; or

(2) If the Secretary finds that the awardee has materially failed to comply with the terms and conditions of the Award or to carry out the purpose for which it was made.

(b) In the event an Award is terminated, the Secretary shall notify the awardee in writing of this determination, the reasons for termination, the effective date, and any procedural rights available.

§ 66.110 Service, payback, and recovery requirements.

(a) Each individual who receives an Award for postdoctoral research or training shall engage in a month of research training, research, or teaching that is health-related (or any combination thereof) for each month of support received, up to a maximum of twelve months. Such period shall be served in accordance with the usual patterns of such employment or training.

(b) In any case in which an individual receives an Award for more than twelve months, the thirteenth month

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and each subsequent month of performing activities under the Award shall be considered to be activities toward satisfaction of the requirement established in paragraph (a) of this section.

(c) Except as provided in § 66.111, an individual subject to the requirements for service in paragraph (a) of this section must begin to undertake the service on a continuous basis within two years after the expiration or termination for his or her Award.

(d) If the individual fails to undertake or perform the service in accordance with the requirements of this section, the United States shall be entitled to recover from the individual an amount determined in accordance with the formula:

$$A = 0 \frac{(t-s)}{(t)}$$

In which

A is the amount the United States is entitled to recover;

0 is the sum of the total amount paid to the individual for the months of postdoctoral support up to a maximum of twelve months;

t is total number of months in the individual's service obligation;

and *s* is the number of months of the obligation served by him or her in accordance with paragraph (a) or (b) of this section.

(e) Except as provided in § 66.111, the individual shall pay to the United States any amount which it is entitled to recover under paragraph (d) of this section within a three-year period beginning on the date the United States becomes entitled to recovery that amount. Interest shall accrue to the United States until any amount due it under paragraph (d) of the section is paid. The rate of interest will be fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to recovery.

[66 FR 29500, May 31, 2001]

§ 66.111 Suspension, waiver, and cancellation.

(a) The Secretary may extend the period for undertaking service described in § 66.110(c), permit breaks in the continuous service required under

§ 66.110(c), or extend the period of repayment under § 66.110(e) if the Secretary determines that:

(1) An extension or break in service is necessary so the individual may complete his or her research training;

(2) Completion during the period would be impossible because the individual is temporarily disabled; or

(3) Completion during the period would involve a substantial hardship to the individual and failure to extend to the period would be against equity and good conscience.

(b) The Secretary may waive, in whole or in part, the obligation of the individual to repay pursuant to § 66.110(d) if the Secretary determines that:

(1) Fulfillment would be impossible because the individual is permanently and totally disabled; or

(2) Fulfillment would involve a substantial hardship to the individual and enforcement of the obligation would be against equity and good conscience.

(c) In making determinations under § 66.111 (a)(3) and (b)(2), the Secretary will take into consideration such factors as:

(1) The individual's present financial resources and obligations;

(2) The individual's estimated future financial resources and obligations;

(3) The reasons for the individual's failure to complete the requirements within the prescribed period, such as problems of a personal nature;

(4) The extent to which the individual has been engaged in activities encompassed by § 66.110(a) and (b);

(5) Whether the individual has received sufficient training to be qualified to perform any such activities;

(6) The unavailability of employment opportunities appropriate to the individual's education and training; and

(7) Any other extenuating circumstances.

(d) Any obligations of any individual under this subpart will be cancelled upon the death of that individual.

[48 FR 24880, June 3, 1983; 48 FR 33710, July 25, 1983, as amended at 66 FR 29500, May 31, 2001]

§ 66.112 Other HHS regulations and policies that apply.

Several other regulations and policies may apply to individuals and institutions receiving payments under this subpart. These include, but are not limited to:

45 CFR part 46—Protection of human subjects

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964

45 CFR part 81—Practice and procedure for hearings under part 80 of this Title

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

51 FR 16958 (May 7, 1986)—NIH Guidelines for Research Involving Recombinant DNA Molecules.

NOTE: This policy is subject to change, and interested persons should contact the Office of Science Policy, Office of Biotechnology Activities, NIH, Suite 302, 6000 Executive Boulevard, MSC 7052, Bethesda, MD 20892-7052, (301) 496-9838 (not a toll-free number) to obtain references to the current version and any amendments.

[49 FR 38116, Sept. 27, 1984, as amended at 66 FR 29500, May 31, 2001]

§ 66.113 Publications.

Publication, distribution, and disposition of all manuscripts and other materials resulting from an Award shall be subject to the conditions that all such materials shall bear appropriate acknowledgement of Department of Health and Human Services support and that the awardee shall furnish copies of these manuscripts or other materials as the Secretary may reasonably request.

§ 66.114 Copyright.

Where the work accomplished under an Award results in a book or other copyrightable material, the author is

free to copyright the work, but the United States reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use, and to authorize others to use, all copyrightable or copyrighted material resulting from the Award.

§ 66.115 Additional conditions.

The Secretary may with respect to any Award or class of Awards impose additional conditions prior to or at the time of any Award when in the Secretary's judgment such conditions are necessary to assure the carrying out of the purposes of the Award, the interests of the public health, or the conservation of funds awarded.

Subpart B—Institutional Grants

§ 66.201 Applicability.

The regulations in this subpart apply to grants under section 487 of the Public Health Service Act, as amended (42 U.S.C. 288), to public institutions and to nonprofit private institutions to enable those institutions to make National Research Service Awards to individuals for research and training to undertake research, in programs specified in section 487 of the Act.

[66 FR 29500, May 31, 2001]

§ 66.202 Definitions.

The definitions in § 66.102 of subpart A of this part apply to this subpart.

[48 FR 24880, June 3, 1983; 48 FR 33710, July 25, 1983]

§ 66.203 Eligibility.

To be eligible for a grant under this subpart, an applicant must be:

- (a) A public or nonprofit private institution; and
- (b) Located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

§ 66.204 Application.

(a) Application for a grant under this subpart shall be made on a form approved for that purpose by the Secretary. Applicants shall submit completed forms on or before the dates the Secretary may prescribe.

(b) In addition to any other pertinent information that the Secretary may require, each application shall set forth in detail:

- (1) The subject area or areas in which the proposed research or training will be conducted;
- (2) The resources and facilities available for use by recipients of Awards in carrying out this research or training;
- (3) The names, qualifications, and experience of the program director and principal staff members who will be responsible for the proposed program;
- (4) The criteria to be employed in selecting recipients of Awards;
- (5) The estimated number of recipients of Awards under the grant;
- (6) The proposed project period and a detailed budget and justification for the amount of grant funds requested; and
- (7) Proposed methods for monitoring and evaluating the performance of individual recipients of Awards, as well as the overall program.

(Approved by the Office of Management and Budget under control number 0925–0022)

§ 66.205 Requirements.

(a) No Award shall be made to an individual from a grant under this subpart unless:

- (1) For any award made for an individual's initial twelve months of NRSA postdoctoral research training, the individual has assured the Secretary, in the form and manner the Secretary may prescribe, that he or she will satisfy the requirements of § 66.110 of subpart A of this part;
 - (2) The individual is a citizen or non-citizen national of the United States or has been lawfully admitted to the United States for permanent residence at the time of the award;
 - (3) The Award includes a provision for termination in the event the recipient is found by the institution to have materially failed to comply with the terms and conditions of the Award or to carry out the purpose for which it was made; and
 - (4) The Award is not to be used to support a residency.
- (b) No Award shall be made to an individual under such grant which would provide that individual with aggregate support in excess of five years for

predoctoral training and three years for postdoctoral training, unless the Secretary for good cause shown as provided in § 66.106(e) of subpart A of this part, waives the application of the limitation with respect to that individual;

(c) The provisions of §§ 66.110 and 66.111 of subpart A of this part constitute terms and conditions of any Award made from a grant under this subpart.

(Approved by the Office of Management and Budget under control number 0925-0022)

[48 FR 24880, June 3, 1983; 48 FR 33710, July 25, 1983, as amended at 66 FR 29501, May 31, 2001]

§ 66.206 Grant awards.

(a) Within the limits of funds available, the Secretary shall award grants to those applicants:

(1) Whose applications have been reviewed and recommended for approval by the appropriate national advisory council or board;

(2) Who have satisfied the requirements of § 66.105; and

(3) Whose proposed programs would, in the judgment of the Secretary, best promote the purposes of section 487(a)(1)(B) of the Act, taking into consideration among other pertinent factors:

(i) The scientific, technical, or educational merit of the proposed program;

(ii) The adequacy of the resources and facilities available to the applicant;

(iii) The qualifications and experience of the program director and principal staff members;

(iv) The degree of the need for personnel in the subject area or areas of the proposed research or training;

(v) The extent to which the applicant, in making Awards, gives special consideration to physicians who agree to undertake a minimum of two years of biomedical research;

(vi) The administrative and management capability of the applicant;

(vii) The reasonableness of the proposed budget in relation to the proposed program; and

(viii) The adequacy of the methods for monitoring and evaluating the performance of individual recipients and the overall program.

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 3-5 years.

(c) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of any approved application.

[48 FR 24880, June 3, 1983, as amended at 66 FR 29501, May 31, 2001]

§ 66.207 Other HHS regulations and policies that apply.

Several other regulations and policies apply to grants under this subpart. These include, but are not limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure

42 CFR part 50, subpart F—Responsibility of applicants for promoting objectivity in research for which PHS funding is sought.

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 46—Protection of human subjects

45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments.

45 CFR part 75—Informal grant appeals procedures

45 CFR part 76—Governmentwide debarment and suspension (non procurement) and governmentwide requirements for drug-free workplace (grants)

§ 66.208

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964

45 CFR part 81—Practice and procedure for hearings under part 80 of this title

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

48 FR 24556—Guidelines for Research Involving Recombinant DNA Molecules published by the National Institutes of Health

51 FR 16958 (May 7, 1986)—NIH Guidelines for Research Involving Recombinant DNA Molecules.

NOTE: This policy is subject to change, and interested persons should contact the Office of Biotechnology Activities, NIH, Suite 302, 6000 Executive Boulevard, MSC 7052, Bethesda, MD 20892-7052, (301) 496-9838 (not a toll-free number) to obtain references to the current version and any amendments.

[49 FR 38116, Sept. 27, 1984, as amended at 66 FR 29501, May 31, 2001]

EDITORIAL NOTE: At 66 FR 20752, May 31, 2001, in § 66.207, the entry for 48 FR 24556 was revised. However, no new entry was set forth.

§ 66.208 Additional conditions.

The Secretary may, with respect to any grant award, impose additional conditions prior to or at the time of any award when in the Secretary's judgment those conditions are necessary to assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

PART 67—AGENCY FOR HEALTH CARE POLICY AND RESEARCH GRANTS AND CONTRACTS

Subpart A—Research Grants for Health Services Research, Evaluation, Demonstration, and Dissemination Projects

Sec.

67.10 Purpose and scope.

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Subpart B—Peer Review of Contracts for Health Services Research, Evaluation, Demonstration, and Dissemination Projects

67.101 Purpose and scope.

67.102 Definitions.

67.103 Peer review of contract proposals.

67.104 Confidentiality.

67.105 Control of data and availability of publications.

AUTHORITY: Pub. L. 103–43, 107 Stat. 214–215, Pub. L. 102–410, 106 Stat. 2094–2101 and sec. 6103, Pub. L. 101–239, 103 Stat. 2189–2208, Title IX of the Public Health Service Act (42 U.S.C. 299–299c–6); and sec. 1142, Social Security Act (42 U.S.C. 1320b–12).

SOURCE: 62 FR 12908, Mar. 18, 1997, unless otherwise noted.

Subpart A—Research Grants for Health Services Research, Evaluation, Demonstration, and Dissemination Projects

§ 67.10 Purpose and scope.

The regulations of this subpart apply to the award by AHCPR of grants and cooperative agreements under:

(a) Title IX of the Public Health Service Act to support research, evaluation, demonstration, and dissemination projects, including conferences, on health care services and systems for the delivery of such services, as well as to establish and operate multidisciplinary health services research centers.

(b) Section 1142 of the Social Security Act to support research on the outcomes, effectiveness, and appropriateness of health care services and procedures, including but not limited to, evaluations of alternative services and procedures; projects to improve methods and data bases for outcomes, effectiveness, and other research; dissemination of research information and clinical guidelines, conferences, and research on dissemination methods.

§ 67.11 Definitions.

As used in this subpart—

Administrator means the Administrator and any other officer or employee of the Agency for Health Care Policy and Research to whom the authority involved may be delegated.

Agency for Health Care Policy and Research (AHCPR) means that unit of the Department of Health and Human Services established by section 901 of the Public Health Service Act.

Direct costs means the costs that can be identified specifically with a particular cost objective, such as compensation of employees for the time and effort devoted specifically to the approved project, and the costs of materials acquired, consumed, or expended specifically for the purpose of the approved project.

Grant means an award of financial assistance as defined in 45 CFR parts 74 and 92, including cooperative agreements.

Grantee means the organizational entity or individual to which a grant, including a cooperative agreement, under Title IX of the Public Health Service Act or section 1142 of the Social Security Act and this subpart is awarded and which is responsible and accountable both for the use of the funds provided and for the performance of the grant-supported project or activities. The grantee is the entire legal entity even if only a particular component is designated in the award document.

Nonprofit as applied to a private entity, means that no part of the net earnings of such entity inures or may lawfully inure to the benefit of any shareholder or individual.

Peer review group means a panel of experts, established under section 922(c) of the PHS Act, who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group as set out in this subpart. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group under this subpart.

PHS Act means the Public Health Service Act, as amended.

Principal investigator means a single individual, designated in the grant application and approved by the Adminis-

trator, who is responsible for the scientific and technical direction of the project.

Social Security Act means the Social Security Act, as amended.

§ 67.12 Eligible applicants.

Any public or nonprofit private entity or any individual is eligible to apply for a grant under this subpart.

§ 67.13 Eligible projects.

Projects for research, evaluations, demonstrations, dissemination of information (including research on dissemination), and conferences, related to health care services and the delivery of such services, are eligible for grant support. These include, but are not limited to, projects in the following categories:

- (a) Effectiveness, efficiency, and quality of health care services;
- (b) Outcomes of health care services and procedures;
- (c) Clinical practice, including primary care and practice-oriented research;
- (d) Health care technologies, facilities, and equipment, including assessments of health care technologies and innovative approaches to such assessments, and technology diffusion;
- (e) Health care costs and financing, productivity, and market forces;
- (f) Health promotion and disease prevention;
- (g) Health statistics and epidemiology;
- (h) Medical liability;
- (i) AID/HIV infection, particularly with respect to issues of access and delivery of health care services;
- (j) Rural health services;
- (k) The health of low-income, minority, elderly, and other underserved populations, including women and children; and
- (l) Information dissemination and research on dissemination methodologies, directed to health care providers, practitioners, consumers, educators, review organizations, and others.

§ 67.14 Application

(a) To apply for a grant, an entity or individual must submit an application in the form and at the time that the

Administrator requires. The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the PHS Act and the Social Security Act, as pertinent, the regulations of this subpart, and any additional terms or conditions of any grant awarded.

(b) In addition to information requested on the application form, the applicant must provide such other information as the Administrator may request.

§ 67.15 Peer review of applications.

(a) General procedures for peer review.

(1) All applications for support under this subpart will be submitted by the Administrator for review to a peer review group, in accordance with section 922(a) of the PHS Act, except that applications eligible for review under section 922(d)(2) of the PHS Act (“small grants”) may be reviewed under adjusted procedures in accordance with paragraph (b) of this section.

(2) Members of the peer review group will be selected based upon their training and experience in relevant scientific and technical fields, taking into account, among other factors:

(i) The level of formal education (e.g., M.A., Ph.D., M.D., D.N.Sc.) completed by the individual and/or the individual’s pertinent experience and expertise;

(ii) The extent to which the individual has engaged in relevant research, the capacities (e.g., principal investigator, assistant) in which the individual has done so, and the quality of such research;

(iii) The extent of the professional recognition received by the individual as reflected by awards and other honors received from scientific and professional organizations outside the Department of Health and Human Services;

(iv) The need of the peer review group to include within its membership experts representing various areas of specialization within relevant scientific and technical fields, or specific health care issues; and

(v) Appropriate representation based on gender, racial/ethnic origin, and geography.

(3) Review by the peer review group under paragraph (a) of this section is conducted by using the criteria set out in paragraph (c) of this section.

(4) The peer review group to which an application has been submitted under paragraph (a) of this section shall make a written report to the Administrator on each application, which shall contain the following parts:

(i) The first part of the report shall consist of a factual summary of the proposed project, including a description of its purpose, scientific approach, location, and total budget.

(ii) The second part of the report shall address the scientific and technical merit of the proposed project with a critique of the proposed project with regard to the factors described in paragraphs (c)(1)(i) through (c)(1)(x) or (c)(2)(i) through (c)(2)(vii) of this section as applicable. This portion of the report shall include a set of recommendations to the Administrator with respect to the disposition of the application based upon its scientific and technical merit. The peer review panel may recommend to the Administrator that an application:

(A) Be given consideration for funding,

(B) Be deferred for a later decision, pending receipt of additional information, or

(C) Not be given further consideration.

(iii) For each application recommended for further consideration by the Administrator, the report shall also provide a priority score based on the scientific and technical merit of the proposed project, and make recommendations on the appropriate project period and level of support. The report may also address, as applicable, the degree to which the proposed project relates to AHCPH-announced priorities.

(b) *Procedural adjustments for small grants.* (1) The Administrator may make adjustments in the peer review procedures established in accordance with paragraph (a) of this section for grant applications with total direct costs that do not exceed the amount specified in section 922(d)(2) of the PHS Act, hereafter referred to as “small grants.”

(2) Non-Federal and Federal experts will be selected by the Administrator for the review of small grant applications on the basis of their training and experience in particular scientific and technical fields, their knowledge of health services research and the application of research findings, and their special knowledge of the issue(s) being addressed or methods and technology being used in the specific proposal.

(3) Review of applications for small grants may be by a review group established in accordance with paragraph (a) of this section, or by individual field readers, or by an ad hoc group of reviewers.

(4) The review criteria set forth in paragraph (c) of this section shall be used for the review of small grant applications.

(5) Each reviewer or group of reviewers to whom an application has been submitted under paragraph (b) of this section shall make a written report to the Administrator on each application. Each report shall summarize the findings of the review and provide a recommendation to the Administrator on whether the application should be given further consideration. For applications recommended for further consideration, the report may also address, as applicable, the degree to which the proposed project relates to AHCPR-announced priorities.

(c) *Review criteria.* The review criteria set out in this paragraph apply to both applications reviewed by peer review panels in accordance with paragraph (a) of this section, and applications for small grants reviewed in accordance with paragraph (b) of this section.

(1) *General review criteria.* In carrying out a review under this section for grants (other than conference grants), the following review criteria will be taken into account, where appropriate:

- (i) The significance and originality from a scientific or technical standpoint of the goals of the project;
- (ii) The adequacy of the methodology proposed to carry out the project;
- (iii) The availability of data or the adequacy of the proposed plan to collect data required in the analyses;
- (iv) The adequacy and appropriateness of the plan for organizing and carrying out the project;

(v) The qualifications and experience of the principal investigator and proposed staff;

(vi) The reasonableness of the budget and the time frame for the project, in relation to the work proposed;

(vii) The adequacy of the facilities and resources available to the grantee;

(viii) The extent to which women and minorities are adequately represented in study populations;

(ix) Where an application involves activities which could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects; and

(x) Any additional criteria that may be announced by the Administrator from time to time for specific categories of grant applications (e.g., proposed projects for support of research centers) eligible for support under this subpart.

(xi) In addition to the scientific and technical criteria above, peer reviewers may be asked to consider the degree to which a proposed project addresses any special AHCPR priorities that have been announced by the Administrator, as applicable.

(2) *Review criteria for conference grants.* In carrying out reviews of conference grants under paragraphs (a) and (b) of this section, the following review criteria will be taken into account, as appropriate:

(i) The significance of the proposed conference, specifically the importance of the issue or problem being addressed, including methodological or technical issues for dealing with the development, conduct, or use of health services research;

(ii) The qualifications of the staff involved in planning and managing the conference;

(iii) The adequacy of the facilities and other resources available for the conference;

(iv) the appropriateness of the proposed budget, including other sources of funding;

(v) The extent to which the health concerns of women and minorities will be addressed in the conference topic(s), as appropriate;

(vi) The plan for evaluating and disseminating the results of the conference; and

(vii) Any additional criteria that may be announced by the Administrator.

(viii) In addition to the scientific and technical criteria above, peer reviewers may be asked to consider the degree to which a proposed project addresses any special AHCPR priorities that have been announced by the Administrator, as appropriate.

(d) *Conflict of interest.* (1) Members of peer review groups will be screened for potential conflicts of interest prior to appointment and will be required to follow Department policies and procedures consistent with the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), Executive Order 12674 (as modified by Executive Order 12731).

(2) In addition to any restrictions referenced under paragraph (d)(1) of this section:

(i) No member of a peer review group (or individual reviewer) may participate in or be present during any review by such group of a grant application in which, to the member's knowledge, any of the following has a financial interest:

(A) The member or his or her spouse, minor child, or partner;

(B) Any organization in which the member is serving as an officer, director, trustee, general partner, or employee; or

(C) Any organization with which the member is negotiating or has any arrangement concerning prospective employment or other similar association, and further;

(ii) In the event that any member of a peer review group or his or her spouse, parent, child, or partner is currently or expected to be the principal investigator or member of the staff responsible for carrying out any research or development activities contemplated as part of a grant application, that member of the group, or the group, may be disqualified from the review and the review conducted by another group with the expertise to do so. An ad hoc group selected in accordance with § 67.15(a), or § 67.15(b) as applicable, may also be used for the review.

Any individual reviewer to whom the conditions of this paragraph apply would also be disqualified as a reviewer.

(iii) No member of a peer review group or individual may participate in any review under this subpart of a specific grant application for which the member has had or is expected to have any other responsibility or involvement (whether preaward or postaward) as an officer or employee of the United States.

(3) Where permissible under the standards and order(s) cited in paragraph (d)(1) of this section, the Administrator may waive the requirements in paragraph (d)(2) of this section if it is determined that there is no other practical means for securing appropriate expert advice on a particular grant application.

[62 FR 12909, Mar. 18, 1997, as amended at 62 FR 37124, July 10, 1997]

§ 67.16 Evaluation and disposition of application.

(a) *Evaluation.* After appropriate peer review in accordance with § 67.15, the Administrator will evaluate applications recommended for further consideration, taking into account, among other factors:

(1) The degree to which the purposes of Title IX of the PHS Act and section 1142 of the Social Security Act, as applicable, are being addressed;

(2) Recommendations made by reviewers pursuant to § 67.15;

(3) Any recommendations made by the National Advisory Council for Health Care Policy, Research, and Evaluation, as applicable;

(4) The appropriateness of the budget;

(5) The extent to which the research proposal and the fiscal plan provide assurance that effective use will be made of grant funds;

(6) The demonstrated business management capability of the applicant;

(7) The demonstrated competence and skill of the staff, especially the senior personnel, in light of the scope of the project;

(8) The probable usefulness of the results of the project for dealing with national health care issues, policies, and programs; and

(9) The degree to which AHCPR-announced priorities or purposes are being addressed.

(b) *Disposition.* On the basis of the evaluation of the application as provided in paragraph (a) of this section, the Administrator shall: give consideration for funding, defer for a later decision, pending receipt of additional information, or give no further consideration for funding, to any application for a grant under this subpart; except that the Administrator may not fund an application which has not been recommended for further consideration as a result of peer review in accordance with § 67.15. A recommendation against further consideration shall not preclude reconsideration, if the application is revised, responding to issues and questions raised during the review, and resubmitted for peer review at a later date.

§ 67.17 Grant award.

(a) Within the limits of available funds, the Administrator may award grants to those applicants whose projects are being considered for funding, which in the judgment of the Administrator, will promote best the purposes of Title IX of the PHS Act and (if applicable) section 1142 of the Social Security Act, AHCPR priorities, and the regulations of this subpart.

(b) The Notice of Grant Award specifies how long the Administrator intends to support the project without requiring the project to re compete for funds. This period, called the project period, will usually be for 3–5 years, except for small grants, which usually are 1 year awards. The project period as specified in the Notice of Grant Award shall begin no later than 9 months following the date of the award, except that the project period must begin in the same fiscal year as that from which funds are being awarded.

(c) Upon request from the grantee, Department grants policy permits an extension of the project period for up to 12 months, without additional funds, when more time is needed to complete the research. The Administrator may approve a request for an additional extension of time based on unusual circumstances with written justification

submitted by the grantee, prior to the completion of the project period. In no case will an additional extension of more than 12 months be approved.

(d) Generally, a grant award will be for 1 year, and subsequent continuation awards will be for 1 year at a time. A grantee must submit a separate continuation application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices and the availability of funds. In all cases, continuation awards require a determination by the Administrator that continuation is in the best interest of the Federal Government.

(e) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application.

(f) *Small grants.* For particular categories of small grants, such as dissertation research support, the Administrator may establish a limit on total direct costs to be awarded. Any categorical limits will be announced in advance of the deadline for receipt of applications for such small grants.

(g) *Supplemental awards.* (1) Except for small grants, supplemental awards that would exceed 20 percent of the AHCPR approved direct costs of the project during the project period, or that request an increase in funds to support a change or a significant expansion of the scope of the project, will be reviewed as competing supplemental grants in accordance with § 67.15(a). A supplemental award for preparation of data in suitable form for transmittal in accordance with § 67.21 shall be excluded from the 20 percent aggregate.

(2) In the case of small grants, as defined in section 922(d)(2) of the PHS Act, the Administrator will not approve a supplemental award during the project period (excluding any supplemental award for preparation of data in suitable form for transmittal in accordance with § 67.21) that will, in the aggregate, exceed 10 percent of the

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AHCPR approved direct costs of the project.

(h) *Noncompeting continuation awards.* Each project with a project period in excess of 2 years and with direct costs over the project period in excess of the amount specified in section 922(d)(2) may be reviewed during the second budget period and during each subsequent budget period by at least two members of the peer review group that reviewed the initial application, or individuals who participated in that review, to the extent practicable. Recommendations to the Administrator for continuation support will be based upon evaluation of:

- (1) The progress of the project in meeting project objectives;
- (2) The appropriateness of the management of the project and allocation of resources within the project;
- (3) The adequacy and appropriateness of the plan for carrying out the project during the budget period in light of the accomplishments during previous budget periods; and
- (4) The reasonableness of the proposed budget for the subsequent budget period.

§ 67.18 Use of project funds.

Grant funds must be spent solely for carrying out the approved project in accordance with Title IX of PHS Act, section 1142 of the Social Security Act (if applicable), the regulations of this subpart, the terms and conditions of the award, and the provisions of 45 CFR part 74, or part 92 for State and local government grantees.

§ 67.19 Other applicable regulations.

Several other regulations apply to grants under this subpart. These include, but are not limited to:

- 37 CFR part 401—Inventions and patents
- 42 CFR part 50 subpart A—Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science
- 42 CFR part 50 subpart D—Public Health Service grant appeals procedure
- 42 CFR part 50 subpart F—Responsibility of applicants for promoting objectivity in research for which PHS funding is sought
- 45 CFR part 16—Procedures of the departmental grant appeals board
- 45 CFR part 46—Protection of human subjects

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- 45 CFR part 74—Administration of grants
- 45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964
- 45 CFR part 81—Practice and procedure for hearings under Part 80 of this title
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 91—Nondiscrimination on the basis of age in DHHS programs or activities receiving Federal financial assistance
- 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements with State and local governments
- 45 CFR part 93—New restrictions on lobbying

§ 67.20 Confidentiality.

The confidentiality of identifying information obtained in the course of conducting or supporting grant and cooperative agreement activities under this subpart is protected by section 903(c) of the PHS Act. Specifically:

(a) No information obtained in the course of conducting or supporting grant and cooperative agreement activities under this subpart, if the entity or individual supplying the information or described in it is identifiable, may be used for any purpose other than the purpose for which it was supplied, unless the identifiable entity or individual supplying the information or described in it has consented to such other use, in the recorded form and manner as the Administrator may require; and

(b) No information obtained in the course of grant and cooperative agreement activities conducted or supported under this subpart may be published or released in other form if the individual who supplied the information or who is described in it is identifiable, unless such individual has consented, in the recorded form and manner as the Administrator may require, to such publication or release.

§ 67.21 Control of data and availability of publications.

Except as otherwise provided in the terms and conditions of the award and subject to the confidentiality requirements of section 903(c) of the PHS Act, section 1142(d) of the Social Security Act, and § 67.20 of this subpart:

(a) All data collected or assembled for the purpose of carrying out health services research, evaluation, demonstration, or dissemination projects supported under this subpart shall be made available to the Administrator, upon request:

(b) All publications, reports, papers, statistics, or other materials developed from work supported, in whole or in part, by an award made under this subpart must be submitted to the Administrator in a timely manner. All such publications must include an acknowledgement that such materials are the results of, or describe, a grant activity supported by AHCPR;

(c) The AHCPR retains a royalty-free, non-exclusive, and irrevocable license to reproduce, publish, use, or disseminate any copyrightable material developed in the course of or under a grant for any purpose consistent with AHCPR's statutory responsibilities, and to authorize others to do so for the accomplishment of AHCPR purposes; and

(d) Except for identifying information protected by section 903(c) of the PHS Act, the Administrator, as appropriate, will make information obtained with AHCPR grant support available, and arrange for dissemination of such information and material on as broad a basis as practicable and in such form as to make them as useful as possible to a variety of audiences, including health care providers, practitioners, consumers, educators, and policymakers.

§ 67.22 Additional conditions.

The Administrator may, with respect to any grant awarded under this subpart, impose additional conditions prior to or at the time of any award when in the Administrator's judgment such conditions are necessary to assure or protect advancement of the approved project, the interest of the public health, or the conservation of grant funds.

Subpart B—Peer Review of Contracts for Health Services Research, Evaluation, Demonstration, and Dissemination Projects**§ 67.101 Purpose and scope.**

(a) The regulations of this subpart apply to the peer review of contracts under:

(1) Title IX of the Public Health Service Act to support research, evaluation, demonstration, and dissemination projects, including conferences, on health care services and systems for the delivery of such services; and development of clinical practice guidelines, quality standards, performance measures, and review criteria.

(2) Section 1142 of the Social Security Act to support research on the outcomes, effectiveness, and appropriateness of health care services and procedures, including, but not limited to, evaluations of alternative services and procedures; projects to improve methods and data bases for outcomes and effectiveness research; dissemination of research information and clinical practice guidelines, as well as quality standards, performance measures, and review criteria; conferences; and research on dissemination methods.

(b) The regulations of this subpart also contain provisions respecting confidentiality of research data, control of data, and availability of information.

§ 67.102 Definitions.

Contract proposal means a written offer to enter into a contract submitted to a contracting officer by an individual or non-Federal organization, and including at a minimum a description of the nature, purpose, duration, cost of project and methods, personnel, and facilities to be utilized in carrying out the requirements of the contract.

Peer review group means a panel of experts, as required by section 922(c) of the PHS Act, established to conduct technical and scientific review of contract proposals and to make recommendations to the Administrator regarding the merits of such proposals.

Request for proposals means a Government solicitation to prospective

offerors, under procedures for negotiated contracts, to submit a proposal to fulfill specific agency requirements based on terms and conditions defined in the solicitation. The solicitation contains information sufficient to enable all offerors to prepare competitive proposals, and is as complete as possible with respect to: The nature of work to be performed; descriptions and specifications of items to be delivered; performance schedule; special requirements, clauses or other circumstances affecting the contract; and criteria by which the proposals will be evaluated.

§ 67.103 Peer review of contract proposals.

(a) All contract proposals for AHCPR support will be submitted by the Administrator for review to a peer review group, as required in section 922(a) of the PHS Act. Proposals will be reviewed in accordance with the Federal Acquisition Regulations and the Health and Human Services Acquisition Regulations (48 CFR Ch. I and III) and the requirements of the pertinent Request for Proposal.

(b) *Establishment of peer review groups.* In accordance with section 922(c) of the PHS Act, the Administrator shall establish such peer review groups as may be necessary to review all contract proposals submitted to AHCPR.

(c) *Composition of peer review groups.* The peer review groups shall be composed of individuals, in accordance with section 922(c) of the PHS Act, as amended, who by virtue of their training or experience are eminently qualified to carry out the duties of such a peer review group. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Members of the peer review group will be selected based upon their training or experience in relevant scientific and technical fields, taking into account, among other factors:

(1) The level of formal education (e.g., M.A., Ph.D., M.D., D.N.Sc.) completed by the individual and/or, as appropriate, the individual's pertinent experience and expertise;

(2) The extent to which the individual has engaged in relevant research, the capacities (e.g., principal

investigator, assistant) in which the individual has done so, and the quality of such research;

(3) The extent of the professional recognition received by the individual as reflected by awards and other honors received from scientific and professional organizations outside the Department of Health and Human Services;

(4) The need of the peer review group to include in its membership experts representing various areas of specialization in relevant scientific and technical fields, or specific health care issues; and

(5) Appropriate representation based on gender, racial/ethnic origin, and geography, to the extent practicable.

(d) *Term of peer review group members.* Notwithstanding section 922(c)(3) of the PHS Act, members of peer review groups appointed to review contract proposals will be appointed to such groups for a limited period of time, as determined by the Administrator; such as on an annual basis, or until the peer review of the contract proposals is completed, or until the expiration of the contract(s) awarded as a result of the peer review.

(e) *Conflict of interest.* (1) Members of peer review groups will be screened for potential conflicts of interest prior to appointment and will be required to follow Department policies and procedures consistent with the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635) and Executive Order 12674 (as modified by Executive Order 12731).

(2) In addition to any restrictions referenced under paragraph (e)(1) of this section:

(i) No member of a peer review group may participate in or be present during any review by such group of a contract proposal in which, to the member's knowledge, any of the following has a financial interest:

(A) The member or his or her spouse, minor child, or partner;

(B) Any organization in which the member is serving as an officer, director, trustee, general partner, or employee; or

(C) Any organization with which the member is negotiating or has any arrangement concerning prospective employment or other similar association, and further;

(ii) In the event any member of a peer review group or his or her spouse, parent, child, or partner is currently or expected to be the project director or member of the staff responsible for carrying out any contract requirements as specified in the contract proposal, that member is disqualified and will be replaced as appropriate.

§ 67.104 Confidentiality.

Identifying information obtained in the course of conducting AHCPR contract activities under this subpart is protected by section 903(c) of the PHS Act. Specifically:

(a) No information obtained in the course of conducting AHCPR contract activities under this subpart, if the entity or individual supplying the information or described in it is identifiable, may be used for any purpose other than the purpose for which it was supplied, unless the identifiable entity or individual supplying the information or described in it has consented to such other use, in the recorded form and manner as the Administrator may require.

(b) No information obtained in the course of conducting AHCPR contract activities under this subpart may be published or released in other form if the individual who supplied the information or who is described in it is identifiable, unless such individual has consented, in the recorded form and manner as the Administrator may require, to such publication or release.

§ 67.105 Control of data and availability of publications.

(a) Data will be collected, maintained, and supplied as provided in each contract subject to the confidentiality requirements of section 903(c) of the PHS Act, section 1142(d) of the Social Security Act, and § 67.104 of this subpart.

(b) All publications, reports, papers, statistics, or other materials developed from work supported in whole or in part by contracts under Title IX of the PHS Act or section 1142 of the Social

Security Act, if applicable, must be submitted to the Administrator in accordance with the terms of the contract. All publications must include an acknowledgment that such materials are the results of, or describe, a contractual activity supported by AHCPR.

(c) In accordance with 48 CFR 52.227-14, unless otherwise specified in the contract, AHCPR will retain a license to use, disclose, reproduce, prepare derivative works from, distribute copies to the public, and perform publicly and display publicly any copyrightable materials produced under a contract for any purpose consistent with AHCPR's statutory responsibilities, and to have or permit others to do so for accomplishment of AHCPR purposes.

(d) Except for identifying information protected by section 903(c) of the PHS Act, the Administrator, as appropriate, will make information provided in accordance with paragraphs (a) and (b) of this section available, and arrange for dissemination of such information and materials on as broad a basis as practicable and in such form as to make them as useful as possible to a variety of audiences, including health care providers, practitioners, consumers, educators, and policymakers.

PART 68a—NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL RESEARCH LOAN REPAYMENT PROGRAM FOR INDIVIDUALS FROM DISADVANTAGED BACK- GROUND (CR-LRP)

Sec.

68a.1 What is the scope and purpose of the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP)?

68a.2 Definitions.

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- 68a.11 How does an individual receive loan repayments beyond the initial two-year contract?
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- 68a.13 Under what circumstances can the service or payment obligation be canceled, waived, or suspended?
- 68a.14 When can a CR-LRP payment obligation be discharged in bankruptcy?
- 68a.15 Additional conditions.
- 68a.16 What other regulations and statutes apply?

AUTHORITY: 42 U.S.C. 288–5.

SOURCE: 63 FR 58312, Oct. 30, 1998, unless otherwise noted.

§ 68a.1 What is the scope and purpose of the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP)?

This part applies to the award of educational loan payments under the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP) authorized by section 487E of the Public Health Service Act (42 U.S.C. 288–5). The purpose of this program is to recruit and retain appropriately qualified health professionals, who are from disadvantaged backgrounds and have substantial educational debt relative to income, to conduct clinical research as NIH employees.

§ 68a.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Applicant means an individual who applies to, and meets the eligibility criteria for the CR-LRP.

Approved clinical research means clinical research approved by the Clinical Research Loan Repayment Committee.

Clinical privileges means the delineation of privileges for patient care granted to qualified health professionals by the NIH Medical Executive Committee or other appropriate credentialing board.

Clinical research means activities which qualify for inclusion as clinical research in the CR-LRP as determined by the Clinical Research Loan Repayment Committee.

Clinical Research Loan Repayment Committee (CR-LRC) means the sci-

entific board assembled to review, rank, and approve or disapprove Clinical Research Loan Repayment Program applications. The CR-LRC is composed of NIH scientific staff and co-chaired by the Associate Director for Clinical Research, NIH, and the Associate Director for Research on Minority Health, NIH. Members are nominated by the Deputy Director, Intramural Research, NIH, and the co-chairs, and appointed by the Director, NIH.

Clinical Research Loan Repayment Program (CR-LRP or Program) means the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds authorized by section 487E of the Act, as amended.

Clinical Research Loan Repayment Program (CR-LRP or Program) contract refers to the agreement, which is signed by an applicant and the Secretary, wherein the applicant from a disadvantaged background agrees to engage in clinical research as an employee of the NIH and the Secretary agrees to repay qualified educational loans for a prescribed period as specified in this part.

Clinical researcher means an NIH employee with clinical privileges who is conducting approved clinical research.

Commercial loans means loans made by banks, credit unions, savings and loan associations, not-for-profit organizations, insurance companies, schools, and other financial or credit institutions which are subject to examination and supervision in their capacity as lending institutions by an agency of the United States or of the State in which the lender has its principal place of business.

Current payment status means that a qualified educational loan is not past due in its payment schedule as determined by the lending institution.

Debt threshold refers to the minimum amount of qualified educational debt an individual must have, on his/her program eligibility date, in order to be eligible for Program benefits and, for purposes of eligibility under this part, debt threshold means that the qualified educational debt must equal or exceed 20 percent of an individual's annual NIH salary on his/her program eligibility date.

Educational expenses means the cost of the health professional's education, including the tuition expenses and other educational expenses such as fees, books, supplies, educational equipment and materials, and laboratory expenses.

Government loans means loans made by Federal, State, county, or city agencies which are authorized by law to make such loans.

Individual from disadvantaged background means an individual who:

(1) Comes from an environment that inhibited the individual from obtaining the knowledge, skill and ability required to enroll in and graduate from a health professions school; or

(2) Comes from a family with an annual income below a level based on low-income thresholds according to family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index, and adjusted by the Secretary for use in all health professions programs. The Secretary periodically publishes these income levels in the FEDERAL REGISTER.

Institute, Center, or Agency (ICA) means an institute, center, or agency of the National Institutes of Health.

Living expenses means the reasonable cost of room and board, transportation and commuting costs, and other reasonable costs incurred during an individual's attendance at an educational institution.

Participant means an individual whose application to the CR-LRP has been approved and whose Program contract has been executed by the Secretary.

Program means the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds.

Program eligibility date means the date on which an individual's Program contract is executed by the Secretary and that individual is engaged in approved clinical research as an employee of the NIH.

Qualified educational loans and interest/debt include Government and commercial educational loans and interest for:

(1) Undergraduate, graduate, and health professional school tuition expenses;

(2) Other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and (3) reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other reasonable living expenses incurred.

Reasonable educational and living expenses means those educational and living expenses which are equal to or less than the sum of the school's estimated standard student budget for educational and living expenses for the degree program and for the year(s) during which the participant was enrolled in school. If there is no standard budget available from the school or if the participant requests repayment for educational and living expenses which exceed the standard student budget, reasonableness of educational and living expenses incurred must be substantiated by additional contemporaneous documentation, as determined by the Secretary.

Repayable debt means the portion, as established by the Secretary, of an individual's total qualified educational debt relative to the NIH salary, which can be paid by the CR-LRP. Specifically, qualifying educational debt amounts in excess of 50 percent of the debt threshold will be considered for repayment.

Salary means base pay plus quarters, subsistence, and variable housing allowances, if applicable.

School means undergraduate, graduate, and health professions schools which are accredited by a body or bodies recognized for accreditation purposes by the Secretary of Education.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service means the Public Health Service.

State means one of the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern

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Mariana Islands, the U.S. Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

Withdrawal means a request by a participant, prior to the Program making payments on his or her behalf, for withdrawal from Program participation. A withdrawal is without penalty to the participant and without obligation to the Program.

§ 68a.3 Who is eligible to apply?

To be eligible to apply to the CR-LRP, an individual must be a citizen, national, or permanent resident of the United States; hold a M.D., Ph.D., D.O., D.D.S., D.M.D., A.D.N./B.S.N., or equivalent degree; have, on his/her program eligibility date, qualified educational debt equal to or in excess of the debt threshold; and be an individual from a disadvantaged background.

§ 68a.4 Who is eligible to participate?

To be eligible to participate in the CR-LRP, an applicant must have the recommendation of the employing ICA Scientific Program Director, the concurrence of the employing ICA Director, and the approval of the CR-LRC. Since participation in the Program is contingent, in part, upon employment with NIH, a Program contract may not be awarded to an applicant until an employment commitment has been made by the employing ICA Personnel Department.

§ 68a.5 Who is ineligible to participate?

The following individuals are ineligible for CR-LRP participation:

(a) Persons who are not eligible applicants as specified under section 68a.3;

(b) Persons who owe an obligation of health professional service to the Federal Government, a State, or other entity, unless a deferral is granted for the length of his/her service obligation under the CR-LRP. The following are examples of programs which have a service obligation: Physicians Shortage Area Scholarship Program, National Research Service Award Program, Public Health Service Scholarship, National Health Service Corps

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Scholarship Program, Armed Forces (Army, Navy, or Air Force) Professions Scholarship Program, Indian Health Service Scholarship Program, and the NIH AIDS Research Loan Repayment Program.

(c) Persons who are not NIH employees, such as Intramural Research Training Award (IRTA) recipients, Visiting Fellows, National Research Service Award (NRSA) recipients, Guest Researchers or Special Volunteers, NIH-National Research Council (NRC) Biotechnology Research Associates Program participants, and Intergovernmental Personnel Act (IPA) participants; or

(d) Persons who do not have clinical privileges.

§ 68a.6 How do individuals apply to participate in the CR-LRP?

An application for participation in the CR-LRP shall be submitted to the NIH office which is responsible for the Program's administration, in such form and manner as the Secretary may prescribe.

§ 68a.7 How are applicants selected to participate in the CR-LRP?

To be selected for participation in the CR-LRP, applicants must satisfy the following requirements:

(a) Applicants must meet the eligibility requirements specified in § 68a.3 and § 68a.4.

(b) Applicants must not be ineligible for participation as specified in § 68a.5.

(c) Applicants must be selected for approval by the CR-LRC, based upon a review of their applications.

§ 68a.8 What does the CR-LRP provide to participants?

(a) Loan repayments: For each year of service the individual agrees to serve, with a minimum of 2 years of obligated service, the Secretary may pay up to \$20,000 per year of a participant's repayable debt.

(b) Under § 68a.8(a), the Secretary will make payments in the discharge of debt to the extent appropriated funds are available for these purposes.

§ 68a.9 What loans qualify for repayment?

(a) The CR-LRP will repay participants' lenders the principal, interest, and related expenses of qualified Government and commercial educational loans obtained by participants for the following:

(1) Undergraduate, graduate, and health professional school tuition expenses;

(2) Other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and

(3) Reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other living expenses as determined by the Secretary.

(b) The following educational loans are ineligible for repayment under the CR-LRP:

(1) Loans obtained from other than a government entity or commercial lending institution;

(2) Loans for which contemporaneous documentation is not available;

(3) Loans or portions of loans obtained for educational or living expenses which exceed the standard of reasonableness as determined by the participant's standard school budget for the year in which the loan was made, and are not determined by the Secretary to be reasonable based on additional documentation provided by the individual;

(4) Loans, financial debts, or service obligations incurred under the following programs: Physicians Shortage Area Scholarship Program (Federal or State), National Research Service Award Program, Public Health and National Health Service Corps Scholarship Training Program, National Health Service Corps Scholarship Program, Armed Forces (Army, Navy, or Air Force) Health Professions Scholarship Program, Indian Health Service Program, and similar programs, upon determination by the Secretary, which provide loans, scholarships, loan repayments, or other awards in exchange for a future service obligation;

(5) Any loan in default or not in a current payment status;

(6) Loan amounts which participants have paid or were due to have paid prior to the program eligibility date; and

(7) Loans for which promissory notes have been signed after the program eligibility date.

§ 68a.10 What does an individual have to do in return for loan repayments received under the CR-LRP?

Individuals must agree to be engaged in approved clinical research, as employees of the NIH, for a minimum initial period of two consecutive years.

§ 68a.11 How does an individual receive loan repayments beyond the initial two-year contract?

An individual may apply for and the Secretary may grant extension contracts for one-year periods, if there is sufficient debt remaining to be repaid and the individual is engaged in approved clinical research as an NIH employee.

§ 68a.12 What will happen if an individual does not comply with the terms and conditions of participation in the CR-LRP?

(a) Absent withdrawal (see § 68a.2) or termination under paragraph (d) of this section, any participant who fails to complete the minimum two-year service obligation required under the Program contract will be considered to have breached the contract and will be subject to assessment of monetary damages and penalties as follows:

(1) Participants who leave during the first year of the initial contract are liable for amounts already paid by the NIH on behalf of the participant plus an amount equal to \$1,000 multiplied by the number of months of the original service obligation.

(2) Participants who leave during the second year of the contract are liable for amounts already paid by the NIH on behalf of the participant plus \$1,000 for each unserved month.

(b) Payments of any amount owed under paragraph (a) of this section shall be made within one year of the participant's breach (or such longer period as determined by the Secretary).

(c) Participants who sign a continuation contract for any year beyond the

initial two-year period and fail to complete the one-year period specified are liable for the pro rata amount of any benefits advanced beyond the period of completed service.

(d) Terminations will not be considered a breach of contract in cases where such terminations are beyond the control of the participant as follows:

(1) Terminations for cause or for convenience of the Government will not be considered a breach of contract and monetary damages will not be assessed.

(2) Occasionally, a participant's research assignment may evolve and change to the extent that the individual is no longer engaged in approved clinical research. Similarly, the research needs and priorities of the ICA and/or the NIH may change to the extent that a determination is made that the health professional's skills may be better utilized in a non-clinical research assignment. Under these circumstances, the following will apply:

(i) Program participation and benefits will cease as of the date an individual is no longer engaged in approved clinical research; and

(ii) Normally, job changes of this nature will not be considered a breach of contract on the part of either the NIH or the participant. Based on the recommendation of the ICA Director and concurrence of the Secretary, the participant will be released from the remainder of his or her service obligation without assessment of monetary penalties. The participant in this case will be permitted to retain all Program benefits made or owed by NIH on his/her behalf up to the date the individual is no longer engaged in approved clinical research, except the pro rata amount of any benefits advanced beyond the period of completed service.

§ 68a.13 Under what circumstances can the service or payment obligation be canceled, waived, or suspended?

(a) Any obligation of a participant for service or payment to the Federal Government under this part will be canceled upon the death of the participant.

(b) The Secretary may waive or suspend any service or payment obligation

incurred by the participant upon request whenever compliance by the participant:

(1) Is impossible,

(2) Would involve extreme hardship to the participant, or

(3) If enforcement of the service or payment obligation would be against equity and good conscience.

(4) The Secretary may approve a request for a suspension of the service or payment obligations for a period of 1 year. A renewal of this suspension may also be granted.

(c) Compliance by a participant with a service or payment obligation will be considered impossible if the Secretary determines, on the basis of such information and documentation as may be required, that the participant suffers from a physical or mental disability resulting in the permanent inability of the participant to perform the service or other activities which would be necessary to comply with the obligation.

(d) In determining whether to waive or suspend any or all of the service or payment obligations of a participant as imposing an undue hardship and being against equity and good conscience, the Secretary, on the basis of such information and documentation as may be required, will consider:

(1) The participant's present financial resources and obligations;

(2) The participant's estimated future financial resources and obligations; and

(3) The extent to which the participant has problems of a personal nature, such as a physical or mental disability or terminal illness in the immediate family, which so intrude on the participant's present and future ability to perform as to raise a presumption that the individual will be unable to perform the obligation incurred.

§ 68a.14 When can a CR-LRP payment obligation be discharged in bankruptcy?

Any payment obligation incurred under § 68a.12 may be discharged in bankruptcy under Title 11 of the United States Code only if such discharge is granted after the expiration of the five-year period beginning on the first date that payment is required and only if the bankruptcy court finds that

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a nondischarge of the obligation would be unconscionable.

§ 68a.15 Additional conditions.

When a shortage of funds exists, participants may be funded partially, as determined by the Secretary. However, once a CR-LRP contract has been signed by both parties, the Secretary will obligate such funds as necessary to ensure that sufficient funds will be available to pay benefits for the duration of the period of obligated service unless, by mutual written agreement between the Secretary and the applicant, specified otherwise. Benefits will be paid on a quarterly basis after each service period unless specified otherwise by mutual written agreement between the Secretary and the applicant. The Secretary may impose additional conditions as deemed necessary.

§ 68a.16 What other regulations and statutes apply?

Several other regulations and statutes apply to this part. These include, but are not necessarily limited to:

Debt Collection Act of 1982, Pub. L. 97-365 (5 U.S.C. 5514);

Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*);

Federal Debt Collection Procedures Act of 1990, Pub. L. 101-647 (28 U.S.C. 1); and

Privacy Act of 1974 (5 U.S.C. 552a).

PART 68c—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT CONTRACEPTION AND INFERTILITY RESEARCH LOAN REPAYMENT PROGRAM

Sec.

68c.1 What is the scope and purpose of the National Institute of Child Health and Human Development (NICHD) Contraception and Infertility Research Loan Repayment Program (CIR-LRP)?

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§ 68c.1 What is the scope and purpose of the National Institute of Child Health and Human Development (NICHD) Contraception and Infertility Research Loan Repayment Program (CIR-LRP)?

This part applies to the award of educational loan payments under the National Institute of Child Health and Human Development (NICHD) Contraception and Infertility Research Loan Repayment Program (CIR-LRP) authorized by section 487B of the Public Health Service Act (42 U.S.C. 288-2). The purpose of this CIR-LRP is the recruitment and retention of highly qualified health professionals to conduct contraception and/or infertility research.

§ 68c.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Allied health professional means:

(1) A physician assistant; or

(2) A research assistant with at least a bachelor's degree and applicable career goals.

Applicant means an individual who applies to, and meets the eligibility criteria for the CIR-LRP.

Commercial loans means loans made by banks, credit unions, savings and loan associations, not-for-profit organizations, insurance companies, schools, and other financial or credit

institutions which are subject to examination and supervision in their capacity as lending institutions by an agency of the United States or of the State in which the lender has its principal place of business.

Contraception and Infertility Research Loan Repayment Program (CIR-LRP or Program) means the NICHD Contraception and Infertility Research Loan Repayment Program authorized by section 487B of the Act.

Contraception and Infertility Research Loan Repayment Program (CIR-LRP or Program) contract refers to the agreement, which is signed by an applicant and the Secretary, wherein the applicant agrees to participate in research on infertility or contraceptive development and the Secretary agrees to repay qualified educational loans for a prescribed period as specified in this part.

Contraception and Infertility Research Loan Repayment Program (CIR-LRP or Program) Panel means a board assembled to review, rank, and approve or disapprove CIR-LRP applications. The Panel is composed of the Deputy Director, NICHD, representatives of NICHD's Office of Administrative Management, respective Program Officers of the Center for Population Research, and other special consultants as required.

Contraceptive development means research whose ultimate goal is to provide new or improved means of preventing pregnancy.

Educational expenses means the cost of the health professional's education, including the tuition expenses and other educational expenses such as fees, books, supplies, educational equipment and materials, and laboratory expenses.

Government loans means loans made by Federal, State, county, or city agencies which are authorized by law to make such loans.

Health professional means an individual who is a physician, Ph.D.-level scientist, nurse, or a graduate student or postgraduate research fellow working toward a degree that will enable them to practice in one of those professions.

Infertility research means research whose long-range objective is to evaluate, treat or ameliorate conditions

which result in the failure of couples to either conceive or bear young.

Living expenses means the reasonable cost of room and board, transportation and commuting costs, and other reasonable costs incurred during an individual's attendance at an educational institution.

Eligible NICHD-supported extramural site means a site funded by NICHD that can be identified as one of the following:

(1) A Cooperative Specialized Contraception and Infertility Research Center;

(2) A Cooperative Specialized Research Center in Reproduction Research;

(3) A Women's Reproductive Health Research Career Development Center; and

(4) Reproductive Medicine Unit identified as a clinical site for the National Cooperative Reproductive Medicine Network, or other sites as designated by the Director.

NICHD intramural laboratory means a laboratory that is supported by the NICHD intramural research program.

Panel means the NICHD Contraception and Infertility Research Loan Repayment Program Panel.

Participant means an individual whose application to the CIR-LRP has been approved and whose Program contract has been executed by the Secretary.

Qualified educational loans include Government and commercial educational loans, interest and related expenses for—

(1) Undergraduate, graduate, and health professional school tuition expenses;

(2) Other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and

(3) Reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other reasonable living expenses incurred.

Reasonable educational and living expenses means those educational and living expenses which are equal to or less than the sum of the school's estimated

standard student budget for educational and living expenses for the degree program and for the year(s) during which the participant was enrolled in school. If there is no standard budget available from the school or if the participant requests repayment for educational and living expenses which exceed the standard student budget, reasonableness of educational and living expenses incurred must be substantiated by additional contemporaneous documentation, as determined by the Secretary.

Research on infertility or contraceptive development means activities which qualify for participation in the CIR-LRP as determined by the Program Panel.

School means undergraduate, graduate, and health professions schools which are accredited by a body or bodies recognized for accreditation purposes by the Secretary of Education.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service means the Public Health Service.

State means one of the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

Withdrawal means an individual's cessation of participation in the Program pursuant to a request by that participant that is implemented by the Secretary prior to the Program making payments on the participant's behalf. A withdrawal is without penalty to the participant and without obligation to the Program.

§ 68c.3 Who is eligible to apply?

To be eligible to apply to the CIR-LRP, an individual must be a qualified health or allied health professional who is at the time of application, or will be at the time of inception into the CIR-LRP, engaged in employment/training at an NICHD intramural lab-

oratory or an eligible NICHD-supported extramural site.

§ 68c.4 Who is eligible to participate?

To be eligible to participate in the CIR-LRP, the applicant must have institutional assurance of employment/affiliation with the NICHD intramural laboratory or eligible NICHD-supported extramural site and approval of the CIR-LRP Panel, must meet the criteria specified in § 68c.3, and not be ineligible to participate under § 68c.5.

§ 68c.5 Who is ineligible to participate?

The following individuals are ineligible for CIR-LRP participation:

- (a) Persons who are not eligible applicants as specified under § 68c.3;
- (b) Persons who owe an obligation of health professional service to the Federal Government, a State, or other entity. The following are examples of programs which have a service obligation: Physicians Shortage Area Scholarship Program, National Research Service Award Program, Public Health Service Scholarship, National Health Service Corps Scholarship Program, Armed Forces (Army, Navy, or Air Force) Professions Scholarship Program, Indian Health Service Scholarship Program, National Health Service Corp Loan Repayment Program, and NIH loan repayment programs.

§ 68c.6 How do individuals apply to participate in the CIR-LRP?

An application for participation in the CIR-LRP shall be submitted to the Center for Population Research, NICHD, NIH, which is responsible for the Program's administration, in such form and manner as the Secretary may prescribe.

§ 68c.7 How are applicants selected to participate in the CIR-LRP?

To be selected for participation in the CIR-LRP, applicants must satisfy the following requirements:

- (a) Applicants must meet the eligibility requirements specified in § 68c.3 and § 68c.4.
- (b) Applicants must not be ineligible for participation as specified in § 68c.5.
- (c) Applicants must propose repayment of a loan that meets the requirements of § 68c.9.

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(d) Applicants must be selected for approval by the CIR-LRP Panel based upon a review of their applications.

§ 68c.8 What does the CIR-LRP provide to participants?

(a) *Loan repayments.* Upon receipt of an individual's written commitment to serve a minimum initial period of two years of obligated service in accordance with this part, the Secretary may pay up to \$35,000 per year of a participant's repayable debt for each year the individual serves.

(b) Under paragraph (a) of this section, the Secretary will make payments in the discharge of debt to the extent appropriated funds are available for that purpose. When a shortage of funds exists, participants may be funded partially, as determined by the Secretary. However, once a CIR-LRP contract has been signed by both parties, the Secretary will obligate such funds as necessary to ensure that sufficient funds will be available to pay benefits for the duration of the period of obligated service unless otherwise specified by mutual written agreement between the Secretary and the applicant. Benefits will be paid on a quarterly basis after each service period unless otherwise specified by mutual written agreement between the Secretary and the applicant.

§ 68c.9 What loans qualify for repayment?

(a) The CIR-LRP will repay participants' lenders the principal, interest, and related expenses of qualified Government and commercial educational loans obtained by participants for the following:

(1) Undergraduate, graduate, and health professional school tuition expenses;

(2) Other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and

(3) Reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other living expenses as determined by the Secretary.

(b) The following educational loans are ineligible for repayment under the CIR-LRP:

(1) Loans obtained from other than a government entity or commercial lending institution;

(2) Loans for which contemporaneous documentation is not available;

(3) Loans or portions of loans obtained for educational or living expenses which exceed the standard of reasonableness as determined by the participant's standard school budget for the year in which the loan was made, and are not determined by the Secretary to be reasonable based on additional documentation provided by the individual;

(4) Loans, financial debts, or service obligations incurred under the following programs: Physicians Shortage Area Scholarship Program (Federal or State), National Research Service Award Program, Public Health and National Health Service Corps Scholarship Training Program, National Health Service Corps Scholarship Program, Armed Forces (Army, Navy, or Air Force) Health Professions Scholarship Program, Indian Health Service Program, and similar programs, upon determination by the Secretary, which provide loans, scholarships, loan repayments, or other awards in exchange for a future service obligation;

(5) Any loan in default or not in a current payment status;

(6) Loan amounts which participants have paid or were due for payment prior to inception into the CIR-LRP; and

(7) Loans for which promissory notes have been signed after the individual's acceptance into the CIR-LRP.

§ 68c.10 What does an individual have to do in return for loan repayments received under the CIR-LRP?

Individuals must make a written commitment in accordance with this part to conduct, and must actually conduct research with respect to contraception and/or infertility at an NICHD intramural laboratory or an eligible NICHD-supported extramural site for a minimum initial period of two years.

§ 68c.11 How does an individual receive loan repayments beyond the initial two-year contract?

An individual may apply for and the Secretary may grant extension contracts for one-year periods, if there is sufficient debt remaining to be repaid and the individual is engaged in research on infertility or contraceptive development at an NICHD intramural laboratory or eligible NICHD-supported extramural site.

§ 68c.12 What will happen if an individual does not comply with the terms and conditions of participation in the CIR-LRP?

(a) Absent withdrawal (see § 68c.2) or termination under paragraph (d) of this section, any participant who fails to begin or complete the minimum two-year service obligation required under the Program contract, will be considered to have breached the contract and will be subject to assessment of monetary damages and penalties as follows:

(1) Participants who leave during the first year of the initial contract are liable for amounts already paid by the CIR-LRP on behalf of the participant plus an amount equal to \$1,000 multiplied by the number of months of the original two-year service obligation.

(2) Participants who leave during the second year of the contract are liable for amounts already paid by the NICHD on behalf of the participant plus \$1,000 for each unserved month.

(b) Participants who sign a continuation contract for any year beyond the initial two-year period and fail to complete the one-year period specified are liable for the pro rata amount of any benefits advanced beyond the period of completed service plus an amount equal to the number of months of obligated service that were not completed by the participant multiplied by \$1,000.

(c) Payments of any amount owed under paragraph (a) or (b) of this section shall be made within one year of the participant's breach (or such longer period as determined by the Secretary).

(d) Terminations will not be considered a breach of contract in cases where such terminations are beyond the control of the participant as follows:

(1) Terminations for cause or for convenience of the Government that are not based upon a breach or default of the participant will not be considered a breach of contract and monetary damages will not be assessed.

(2) The participant transfers to another NICHD intramural laboratory or eligible NICHD-supported extramural site, in which case the participant remains bound to any and all obligations of the contract.

(3) The participant transfers to a site other than an NICHD intramural laboratory or eligible NICHD-supported extramural site, in which case the participant may not be assessed monetary penalties if, in the judgement of the CIR-LRP Panel, the participant continues to engage in contraception and/or infertility research for any remaining period of obligated service as set forth in the contract.

§ 68c.13 Under what circumstances can the service or payment obligation be canceled, waived, or suspended?

(a) Any obligation of a participant for service or payment to the Federal Government under this part will be canceled upon the death of the participant.

(b)(1) The Secretary may waive or suspend any service or payment obligation incurred by the participant upon request whenever compliance by the participant:

- (i) Is impossible;
- (ii) Would involve extreme hardship to the participant; or
- (iii) If enforcement of the service or payment obligation would be against equity and good conscience.

(2) The Secretary may approve a request for a suspension of the service or payment obligations for a period of 1 year. A renewal of this suspension may also be granted.

(c) Compliance by a participant with a service or payment obligation will be considered impossible if the Secretary determines, on the basis of information and documentation as may be required, that the participant suffers from a physical or mental disability resulting in the permanent inability of the participant to perform the service or other

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activities which would be necessary to comply with the obligation.

(d) In determining whether to waive or suspend any or all of the service or payment obligations of a participant as imposing an undue hardship and being against equity and good conscience, the Secretary, on the basis of information and documentation as may be required, will consider:

(1) The participant's present financial resources and obligations;

(2) The participant's estimated future financial resources and obligations; and

(3) The extent to which the participant has problems of a personal nature, such as a physical or mental disability or terminal illness in the immediate family, which so intrude on the participant's present and future ability to perform as to raise a presumption that the individual will be unable to perform the obligation incurred.

§ 68c.14 When can a CIR-LRP payment obligation be discharged in bankruptcy?

Any payment obligation incurred under § 68c.12 may be discharged in

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bankruptcy under Title 11 of the United States Code only if such discharge is granted after the expiration of the five-year period beginning on the first date that payment is required and only if the bankruptcy court finds that a nondischarge of the obligation would be unconscionable.

§ 68c.15 Additional conditions.

In order to protect or conserve Federal funds or to carry out the purposes of section 487B of the Act, or of this subpart, the Secretary may impose additional conditions as a condition of any approval, waiver or suspension authorized by this subpart.

§ 68c.16 What other regulations and statutes apply?

Several other regulations and statutes apply to this part. These include, but are not necessarily limited to:

Debt Collection Act of 1982, Public Law 97-365 (5 U.S.C. 5514);

Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*);

Federal Debt Collection Procedures Act of 1990, Public Law 101-647 (28 U.S.C. 1); and

Privacy Act of 1974 (5 U.S.C. 552a).